

# Exhibit 4

Karla Ballman, Ph.D.

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IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NEW JERSEY

- - -

IN RE: JOHNSON & :  
JOHNSON TALCUM POWDER :  
PRODUCTS MARKETING, :  
SALES PRACTICES, AND : NO. 16-2738  
PRODUCTS LIABILITY : (FLW) (LHG)  
LITIGATION :  
:

THIS DOCUMENT RELATES :  
TO ALL CASES :

- - -

March 22, 2019

- - -

Videotaped deposition of  
KARLA BALLMAN, Ph.D., taken pursuant to  
notice, was held at Skadden Arps, Four  
Times Square, New York, New York,  
beginning at 9:04 a.m., on the above  
date, before Michelle L. Gray, a  
Registered Professional Reporter,  
Certified Shorthand Reporter, Certified  
Realtime Reporter, and Notary Public.

- - -

GOLKOW LITIGATION SERVICES  
877.370.3377 ph| 917.591.5672  
deps@golkow.com

Karla Ballman, Ph.D.

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APPEARANCES:

LEVIN PAPANTONIO THOMAS

MITCHELL RAFFERTY & PROCTOR, PA

BY: CHRISTOPHER V. TISI, ESQ.

316 South Baylen Street,

Suite 600

Pensacola, Florida 32502

(888) 435-7001

Ctisi@levinlaw.com

- and -

LUNDY, LUNDY, SOILEAU & SOUTH, LLP

BY: RUDIE R. SOILEAU, JR., ESQ.

501 Broad Street

Lake Charles, Louisiana 70601

(337) 439-0707

Rudiesoileau@gmail.com

- and -

RESTAINO LAW, LLC

BY: JOHN M. RESTAINO, JR., DPM, ESQ.

130 Forest Street

Denver, Colorado 80220

(303) 839-8000

Jrestaino@restainollc.com

Representing the Plaintiffs

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24

APPEARANCES: (Cont'd.)

SEYFARTH SHAW, LLP

BY: THOMAS T. LOCKE, ESQ.

975 F Street, NW

Washington, D.C. 20004

(202) 463-2400

tlocke@seyfarth.com

Representing the Defendant, PCPC

TELEPHONIC APPEARANCES:

ASHCRAFT & GEREL, LLP

BY: MICHELLE A. PARFITT, ESQ.

4900 Seminary Road, Suite 650

Alexandria, Virginia 22311

(703) 931-5500

mparf@aol.com

Representing the Plaintiffs

ALSO PRESENT:

VIDEOTAPE TECHNICIAN:

Henry Marte

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APPEARANCES: (Cont'd.)

SKADDEN ARPS, LLP

BY: JESSICA D. MILLER, ESQ.

1440 New York Avenue, N.W.

Washington, D.C. 20005

(202) 371-7850

Jessica.miller@skadden.com

- and -

DRINKER, BIDDLE & REATH, LLP

BY: SUSAN M. SHARKO, ESQ.

600 Campus Drive

Florham Park, New Jersey 07932

(973) 549-7000

susan.sharko@dbr.com

- and -

DRINKER BIDDLE & REATH, LLP

BY: KATHERINE MCBETH, ESQ.

One Logan Square,

Suite 2000

Philadelphia, Pennsylvania 19103

(215) 988-2706

katherine.mcbeth@dbr.com

Representing the Defendants, Johnson

& Johnson entities

TUCKER ELLIS, LLP

BY: MICHAEL ANDERTON, ESQ.

950 Main Avenue, Suite 1100

Cleveland, Ohio 44113

(216) 696-4835

Michael.anderton@tuckerellis.com

Representing the Defendant, PTI

Royston LLC and PTI Union LLC

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Testimony of:

KARLA BALLMAN, Ph.D.

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<p style="text-align: right;">Page 11</p> <p>1           - - -</p> <p>2           DEPOSITION SUPPORT INDEX</p> <p>3           - - -</p> <p>4</p> <p>5       Direction to Witness Not to Answer</p> <p>6       PAGE   LINE</p> <p>      None.</p> <p>7</p> <p>8       Request for Production of Documents</p> <p>9       PAGE   LINE</p> <p>      None.</p> <p>10</p> <p>11       Stipulations</p> <p>12       PAGE   LINE</p> <p>      None.</p> <p>13</p> <p>14       Questions Marked</p> <p>15       PAGE   LINE</p> <p>      None.</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 13</p> <p>1           - - -</p> <p>2           EXAMINATION</p> <p>3           - - -</p> <p>4       BY MR. TISI:</p> <p>5           Q.   Good morning?</p> <p>6           A.   Good morning.</p> <p>7           Q.   Would you please state your</p> <p>8           name.</p> <p>9           A.   Karla Ballman.</p> <p>10          Q.   And it's Karla Ballman,</p> <p>11          Ph.D.?</p> <p>12          A.   Well, that's my degree, is a</p> <p>13          Ph.D.</p> <p>14          Q.   Correct. You know that</p> <p>15          you've been identified by Johnson &amp;</p> <p>16          Johnson lawyers as an expert in the</p> <p>17          talcum powder litigation?</p> <p>18          A.   Yes. I've been retained by</p> <p>19          Johnson &amp; Johnson as an expert.</p> <p>20          Q.   Okay. At the request of</p> <p>21          Johnson &amp; Johnson's lawyers, did you</p> <p>22          prepare an expert report on behalf of</p> <p>23          Johnson &amp; Johnson?</p> <p>24          A.   I did prepare an expert</p>

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<p>1 report.</p> <p>2 Q. Okay. And I'd like to have</p> <p>3 that marked as Exhibit Number 1.</p> <p>4 (Document marked for</p> <p>5 identification as Exhibit</p> <p>6 Ballman-1.)</p> <p>7 BY MR. TISI:</p> <p>8 Q. Now Dr. Ballman, does</p> <p>9 this -- does this report that you issued</p> <p>10 address the epidemiologic question about</p> <p>11 whether talcum powder products are</p> <p>12 capable of causing ovarian cancer?</p> <p>13 A. Yes. I had been asked to</p> <p>14 look at all the evidence and totality and</p> <p>15 come to -- to determine whether or not</p> <p>16 ovarian cancer -- I mean talcum powder</p> <p>17 causes ovarian cancer.</p> <p>18 Q. Okay. And you reached that</p> <p>19 to a reasonable degree of medical</p> <p>20 certainty?</p> <p>21 A. My -- my expertise is in</p> <p>22 epidemiology and statistics, and so I</p> <p>23 reached it to a reasonable degree of</p> <p>24 certainty coming from it, from an</p>	<p>1 This question -- this report</p> <p>2 addresses the question about whether or</p> <p>3 not, in your opinion, to a reasonable</p> <p>4 degree of certainty, that talcum powder</p> <p>5 products cause or does not cause ovarian</p> <p>6 cancer.</p> <p>7 A. Yeah. So this report</p> <p>8 describes the -- what I went through to</p> <p>9 look at the data in totality with respect</p> <p>10 to the question as to whether there is</p> <p>11 evidence to support the hypothesis that</p> <p>12 talcum powder applied to the perineum</p> <p>13 causes ovarian cancer.</p> <p>14 Q. And in fact, the cover page</p> <p>15 which you signed says "Expert Report of</p> <p>16 Karla Ballman Ph.D. for General Causation</p> <p>17 Daubert Hearing."</p> <p>18 Do you see that?</p> <p>19 A. Okay. I see that. So I</p> <p>20 didn't know what the legal terms were.</p> <p>21 So I did do this report, yes.</p> <p>22 Q. And this report is your</p> <p>23 assessment of both the epidemiologic and</p> <p>24 non-epidemiologic evidence through a</p>
Page 15	Page 17
<p>1 epidemiology standpoint. I'm not sure</p> <p>2 what you mean by medicine. I'm not an</p> <p>3 M.D.</p> <p>4 Q. Okay. What does reasonable</p> <p>5 degree of certainty mean to you?</p> <p>6 A. It means that I don't see</p> <p>7 any evidence that supports that</p> <p>8 hypothesis.</p> <p>9 Q. Okay. No evidence?</p> <p>10 A. Credible evidence.</p> <p>11 Q. The report that you issued</p> <p>12 is your epidemiologic assessment of that</p> <p>13 general causation question about whether</p> <p>14 talcum powder products is capable of</p> <p>15 causing ovarian cancer, true?</p> <p>16 A. What do you mean by general</p> <p>17 causation? I know that lawyers use</p> <p>18 different words than what I use. And</p> <p>19 they place a lot of emphasis on the words</p> <p>20 they use, like I do on the numbers. So</p> <p>21 I'm not quite sure what you mean by</p> <p>22 general causation.</p> <p>23 Q. Whether or not -- let's take</p> <p>24 the word general causation out.</p>	<p>1 framework that we will be talking about</p> <p>2 today called the Bradford Hill framework,</p> <p>3 correct?</p> <p>4 A. What do you mean by</p> <p>5 non-epidemiologic?</p> <p>6 Q. I think I used -- those were</p> <p>7 the words that you used in the report.</p> <p>8 A. Did I? Can you point me to</p> <p>9 the page where I used those words?</p> <p>10 Q. I'm not going to waste my</p> <p>11 time to do it. But you -- I think you</p> <p>12 talked about that you were looking at</p> <p>13 both the observational studies and the</p> <p>14 non-observational evidence?</p> <p>15 MS. MILLER: Objection.</p> <p>16 THE WITNESS: So as -- as an</p> <p>17 expert in epidemiology and</p> <p>18 statistics, and I do this like day</p> <p>19 in and day out, as part of my</p> <p>20 life, I look at the totality of</p> <p>21 the evidence.</p> <p>22 So some of the evidence</p> <p>23 involved human. And some of the</p> <p>24 evidence may involve some animal</p>

5 (Pages 14 to 17)

Karla Ballman, Ph.D.

<p style="text-align: right;">Page 18</p> <p>1 experiments, and some evidence I 2 look at might involve some cell 3 line experiments. 4 BY MR. TISI: 5 Q. Okay. And we'll talk about 6 that. We'll talk about that for sure. 7 In collecting that evidence 8 did you organize your evidence 9 considering what I think the record will 10 reflect is the Bradford Hill framework? 11 A. Within my report I do have 12 sections that go through the Bradford 13 Hill framework. 14 Q. Okay. And you know what the 15 Bradford Hill framework is, correct? 16 A. I do. 17 Q. And after collecting the 18 evidence, did you then weigh the 19 evidence? 20 A. So weigh it in what respect? 21 Q. I'm asking you, how did 22 you -- how did you -- well, we'll come 23 back to this. 24 But you looked at the</p>	<p style="text-align: right;">Page 20</p> <p>1 Q. Okay. And that's your 2 opinion? 3 A. I just work with -- I don't 4 think that's my opinion. I think it's 5 the basis of what all epidemiologists put 6 together as -- 7 Q. And so it's your opinion 8 that all epidemiologists agree that 9 cohort studies are better than 10 case-control studies? 11 MS. MILLER: Objection. 12 THE WITNESS: Again, it 13 depends. Are you saying cohort 14 studies in general -- 15 BY MR. TISI: 16 Q. Yes. Prospective -- 17 A. -- or are you talking 18 about -- 19 Q. Prospective cohort studies 20 are better than case-control studies on 21 your hierarchy of evidence. 22 MS. MILLER: Objection. 23 THE WITNESS: You know, 24 again, it depends. That's a</p>
<p style="text-align: right;">Page 19</p> <p>1 evidence and you decided which evidence, 2 if any, was credible or not, correct? 3 A. I looked at the evidence in 4 totality. And what I -- and I think I 5 lay out in my report, you know, there -- 6 there is sort of a general hierarchy of 7 epidemiologic evidence that goes from, 8 like, lowest -- it's like a pyramid. I 9 think it's Figure 2 in my report -- up to 10 the highest evidence. And that's the 11 type of weight I put on it. 12 So, for instance, I place 13 sort of evidence coming out of -- bless 14 you -- cohort studies higher than 15 evidence coming out of case-control 16 studies. 17 Q. Okay. And your -- and we'll 18 talk about this. But your opinion is 19 that cohort studies are stronger 20 evidence, more reliable evidence than 21 case -- case-control studies? 22 A. I believe epidemiology, 23 that's a fairly well established 24 principle.</p>	<p style="text-align: right;">Page 21</p> <p>1 pretty general thing. I'm just 2 saying that if you -- you look in 3 epidemiology textbooks, if you 4 look in any other places where 5 this is discussed, cohort studies 6 as a whole in general are placed 7 higher than the evidence coming 8 out of case-control studies. 9 BY MR. TISI: 10 Q. And we'll talk about that. 11 But that's one of the guiding foundations 12 of your expert opinion, correct? 13 MS. MILLER: Objection. 14 THE WITNESS: It's again 15 established in the epidemiology 16 literature, and I just applied 17 that to the evidence that I 18 assessed. 19 BY MR. TISI: 20 Q. Okay. Actually my question 21 is different, Doctor. 22 That's one of the guiding 23 principles of your expert report that -- 24 MS. MILLER: Object --</p>

6 (Pages 18 to 21)

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<p style="text-align: right;">Page 22</p> <p>1 BY MR. TISI:</p> <p>2 Q. -- you have weighed --</p> <p>3 MR. TISI: Wait.</p> <p>4 MS. MILLER: Sorry.</p> <p>5 BY MR. TISI:</p> <p>6 Q. -- that you have weighed</p> <p>7 cohort studies as a whole higher than</p> <p>8 case-control studies as a whole.</p> <p>9 MS. MILLER: Objection.</p> <p>10 She's asked -- she's answered this</p> <p>11 question like four times.</p> <p>12 THE WITNESS: And with all</p> <p>13 the interruptions, again, can --</p> <p>14 BY MR. TISI:</p> <p>15 Q. I'll rephrase the question.</p> <p>16 Okay. You asked what other</p> <p>17 epidemiologists do, and I'm asking you</p> <p>18 what you did.</p> <p>19 For the purposes of your</p> <p>20 report, did you -- the framework in which</p> <p>21 you looked at the different studies, you</p> <p>22 placed cohort studies higher than</p> <p>23 case-control studies?</p> <p>24 MS. MILLER: Same objection.</p>	<p style="text-align: right;">Page 24</p> <p>1 A. What I found is in the</p> <p>2 case-control studies, about 50 percent of</p> <p>3 the studies had a statistically</p> <p>4 significant result with regard to the</p> <p>5 association between talcum powder use and</p> <p>6 ovarian cancer. And I found within the</p> <p>7 cohort studies none of them had a</p> <p>8 statistically significant association</p> <p>9 between the use of perineal talcum powder</p> <p>10 and ovarian cancer.</p> <p>11 Q. And it was your opinion that</p> <p>12 the nonstatistically significant results</p> <p>13 were inconsistent with the statistically</p> <p>14 significant results?</p> <p>15 A. So if -- if some -- one</p> <p>16 thing is statistically significant and</p> <p>17 another thing is not statistically</p> <p>18 significant, those are two different</p> <p>19 things.</p> <p>20 Q. Okay. They may be two</p> <p>21 different things, but is it your opinion</p> <p>22 that they are contrary to each other?</p> <p>23 They are inconsistent?</p> <p>24 A. So when -- when I looked at</p>
<p style="text-align: right;">Page 23</p> <p>1 Just make sure you give me</p> <p>2 time to object.</p> <p>3 THE WITNESS: Thank you.</p> <p>4 So again, I looked at the</p> <p>5 evidence in totality and saw what</p> <p>6 it looked like. I applied</p> <p>7 established epidemiology</p> <p>8 principles that say cohort studies</p> <p>9 have higher degree of evidence for</p> <p>10 causality above case-control</p> <p>11 studies.</p> <p>12 BY MR. TISI:</p> <p>13 Q. And you relied, and we'll</p> <p>14 talk about this, the hierarchy, you</p> <p>15 referred to that as levels of evidence</p> <p>16 throughout your report, correct?</p> <p>17 A. I believe I do.</p> <p>18 Q. Okay. And you also found,</p> <p>19 and we'll talk about this, that the</p> <p>20 statistically significant results in the</p> <p>21 case-control studies were inconsistent</p> <p>22 and -- and contrary to the</p> <p>23 nonstatistically significant results of</p> <p>24 the non-case-control studies, correct?</p>	<p style="text-align: right;">Page 25</p> <p>1 the cohort studies, I believe --</p> <p>2 case-control studies, I want to make</p> <p>3 sure -- I believe that the range of -- of</p> <p>4 the risk ratios that -- that were shown</p> <p>5 went about -- were about fourfold and</p> <p>6 were higher than the cohort studies of</p> <p>7 which their range was maybe about</p> <p>8 1.75-fold, so much tighter and lower.</p> <p>9 Q. Okay. But my question is</p> <p>10 different. I'm focusing on statistical</p> <p>11 significance now.</p> <p>12 Is it your opinion that the</p> <p>13 nonstatistically significant results were</p> <p>14 contrary to the statistically significant</p> <p>15 results in the studies irrespective of</p> <p>16 study design?</p> <p>17 MS. MILLER: Objection.</p> <p>18 THE WITNESS: So I'm not</p> <p>19 sure what you mean as contrary.</p> <p>20 And what statisticians, how</p> <p>21 statisticians and epidemiologists</p> <p>22 approach problems is you assume</p> <p>23 the null hypothesis is true, which</p> <p>24 would mean no association, and</p>

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<p>1 then you look to see if there's 2 evidence of an association. 3 So the cohort studies found 4 no evidence of an association and 5 about half of the -- in a 6 statistically significant sense, 7 and about half of the case-control 8 studies found a statistically 9 significant association. 10 BY MR. TISI: 11 Q. And so because of your -- 12 your opinion that statistically 13 significant results, insignificant 14 results prove the null, and -- and 15 statistically significant results suggest 16 an association, those two conflict with 17 each other and, therefore, we have 18 inconsistency? 19 MS. MILLER: Objection. 20 That mischaracterizes her 21 testimony. 22 THE WITNESS: So first of 23 all, you can't prove the null. 24 BY MR. TISI:</p>	<p>1 results are inconsistent with the 2 statistically insignificant results? 3 MS. MILLER: Objection. 4 We've now asked and answered this 5 I think ten times. 6 MR. TISI: Well, she hasn't 7 answered it. 8 BY MR. TISI: 9 Q. Go ahead. 10 MS. MILLER: I disagree. 11 BY MR. TISI: 12 Q. Are they -- are they 13 inconsistent in your opinion? 14 A. I believe, as I said, the 15 cohort studies find no association. 16 Q. Right. 17 A. And the case-control 18 studies, some of them find an 19 association, some do not. 20 Q. And so those are 21 inconsistent? 22 MS. MILLER: Objection. 23 THE WITNESS: Those are 24 clearly different.</p>
Page 27	Page 29
<p>1 Q. Okay. 2 A. Okay. And so, again, you 3 assume until -- it's sort of like law. 4 You assume innocence until proven guilty. 5 Q. Okay. 6 A. And so you assume no 7 association, and you have to see whether 8 or not there is evidence of an 9 association. 10 Q. Okay. So changing that a 11 little bit -- 12 MS. MILLER: Were you done? 13 Were you done answering? 14 THE WITNESS: Well, I'll -- 15 I was going to repeat again is 16 that in the cohort studies they 17 consistently found no association, 18 whereas in the case-control 19 studies, even among themselves, 20 some found an association and some 21 did not. 22 BY MR. TISI: 23 Q. Okay. And so your -- your 24 view was that statistically significant</p>	<p>1 BY MR. TISI: 2 Q. And so are they 3 inconsistent? 4 MS. MILLER: Objection. 5 THE WITNESS: Those -- those 6 again are clearly different. And 7 so if -- if -- I think it would be 8 a different situation if -- if, 9 you know, every single study found 10 an association which was not the 11 case here. 12 BY MR. TISI: 13 Q. Okay. But consistency is 14 one of the elements of the Bradford Hill 15 criteria, right? 16 A. That is correct. 17 Q. Okay. So I'm using a term 18 of art, okay. 19 Is it your opinion that -- 20 that the -- the statistically significant 21 results are inconsistent with the 22 statistically not significant results? 23 A. I think what I said and what 24 Bradford Hill said, that there -- there</p>

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<p>1 are two ways of looking at consistency. 2 The first level is whether 3 or not they are coming up with 4 statistical significance or not. So 5 the -- the case-control studies were 6 mixed with that. And the cohort studies 7 all came up with an -- a nonsignificant 8 result. 9 Q. Okay. So those are 10 inconsistent -- in your opinion. I 11 just -- I really want to focus on my -- 12 my question. 13 Is it your opinion that the 14 nonstatistically significant results that 15 you described of the cohort and some of 16 the case-control studies are inconsistent 17 with the case-controlled studies that 18 showed a statistically significant 19 result? 20 A. And again, I -- I don't know 21 how to answer other than to say that 22 there is a difference between something 23 that's statistically significant and 24 something that's not.</p>	<p>1 She's been dancing around the 2 question. 3 THE WITNESS: So the 4 case-control studies generally 5 report risk ratios greater than 6 one. A little over half are 7 statistically significant. And 8 the range of the magnitude of the 9 estimate is quite large. There's 10 no consistency between the -- 11 MS. SHARKO: You've got to 12 read much slower. 13 MR. TISI: We're going to 14 have one or two. We're going to 15 back to what you said -- what you 16 said to me yesterday, that we only 17 have one person. 18 MS. MILLER: All she said 19 was that she should read more 20 slowly. 21 MR. TISI: I understand. 22 MS. MILLER: I can tell her 23 that. 24 MR. LOCKE: If you would</p>
Page 31	Page 33
<p>1 If that's your definition of 2 inconsistency, then in that regard, they 3 are inconsistent. 4 Q. Doctor, I -- you applied the 5 Bradford Hill criteria which is 6 consistency is an element. And I'm 7 asking you, using that framework, are 8 statistically significant results that 9 you have described inconsistent with the 10 statistically significant results? 11 A. So give me a minute here. I 12 want to make -- I'm thinking perhaps I 13 stated it more clearly in here. 14 So it's my opinion that the 15 consistency of the association criteria 16 has not been demonstrated. 17 Q. And is that because there 18 are statistically significant results on 19 one hand and statistically insignificant 20 results on the other hand? 21 MS. MILLER: Objection. I 22 think she's now asked and answered 23 this 20 times. 24 MR. TISI: She hasn't.</p>	<p>1 encourage that, that was something 2 that you did in breach. 3 BY MR. TISI: 4 Q. Go ahead. 5 MS. MILLER: If you read too 6 quickly, the court reporter can't 7 take it down. 8 THE WITNESS: Sorry about 9 that. 10 So "Although the 11 case-control studies generally 12 report risk ratios greater than 13 one, and a little over half of the 14 studies had statistically 15 significant results, the range of 16 the magnitude is quite large." 17 And then I do say, "More 18 importantly there is no 19 consistency between the 20 case-control studies and the 21 cohort studies." 22 BY MR. TISI: 23 Q. And is that in part because 24 of the statistical significance?</p>

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<p>1 MS. MILLER: Objection. 2 THE WITNESS: I think I 3 just -- I just stated that there. 4 BY MR. TISI: 5 Q. Okay. Then that's -- then 6 that's the answer. I appreciate that. 7 Okay. Could you turn to 8 Page 53 of your -- first of all, after 9 weighing the evidence, did you reach a 10 conclusion about the causation question? 11 MS. MILLER: Objection. 12 Vague. 13 THE WITNESS: Yeah. What -- 14 MR. TISI: Okay. Let me ask 15 the question. 16 BY MR. TISI: 17 Q. After weighing all the 18 evidence that you collected, did you 19 reach a conclusion about whether, in your 20 opinion, to a reasonable degree of 21 certainty, that talcum powder does or 22 does not cause ovarian cancer? 23 A. So it is my professional 24 opinion that there is no evidence of a</p>	<p>1 principles in reaching that 2 conclusion. 3 BY MR. TISI: 4 Q. Okay. And in applying those 5 principles in your judgment, there is no 6 evidence of causation, true? 7 MS. MILLER: Objection. 8 That mischaracterizes the 9 testimony again. 10 MR. TISI: I'm asking the 11 question. I'm asking -- 12 MS. MILLER: Yeah, but 13 you're mischaracterized her 14 testimony. 15 MR. TISI: I'm asking her a 16 question, Counsel. You are -- 17 MS. MILLER: 18 Mischaracterizing her testimony. 19 MR. TISI: Fine, object. 20 MS. MILLER: I am. 21 MR. TISI: Good. 22 THE WITNESS: May you repeat 23 that, please. 24 BY MR. TISI:</p>
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<p>1 causal relationship between talcum powder 2 exposure and ovarian cancer. 3 Q. And you used your 4 professional judgment based upon your 5 experience and training to reach that 6 conclusion? 7 A. It's based on my extensive 8 and rigorous review of the epidemiology 9 studies, and to some extent my review of 10 the scientific literature and my 11 experience and expertise in assessing 12 studies for level of evidence of the 13 data. 14 Q. Okay. And did you use your 15 professional judgment in reaching that 16 conclusion? 17 A. I don't know what you mean 18 by professional judgment. 19 Q. Did you -- did you use your 20 judgment in looking at the data? 21 A. I -- 22 MS. MILLER: Objection. 23 THE WITNESS: I'm sorry. 24 I applied epidemiological</p>	<p>1 Q. Yes, in your judgment based 2 upon your analysis of the evidence, the 3 epidemiologic and non-epidemiologic 4 evidence, you have concluded that there 5 is no risk of ovarian cancer with talcum 6 powder products? 7 MS. MILLER: Objection. 8 Same objection. 9 THE WITNESS: I'm sorry. I 10 keep not -- 11 I believe I said that I 12 applied established 13 epidemiological principles in 14 evaluating the data in totality 15 and came to the conclusion that 16 the evidence does not support a 17 causal relationship between talcum 18 powder exposure and ovarian 19 cancer. 20 BY MR. TISI: 21 Q. Now, if you look on Page 53, 22 of your report you have a conclusion. 23 A. Yes. 24 Q. And on the conclusion, you</p>

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<p>1 state the following. You state, "In my 2 professional opinion, there is no 3 evidence of a causal relationship between 4 perineal genital talcum powder exposure 5 and ovarian cancer. This is based on my 6 extensive and rigorous review of the 7 epidemiology studies, and to a lesser 8 extent my review of the scientific 9 literature, and my experience and 10 expertise in assessing studies for the 11 level of evidence in the data." 12 Did I read that correctly? 13 A. You did read that correctly. 14 Q. And that is your opinion? 15 A. It's what I wrote there. 16 Q. Okay. I'm going to mark, 17 just so we don't have to read the whole 18 report and come back to that. 19 (Document marked for 20 identification as Exhibit 21 Ballman-2.) 22 MR. TISI: This is your 23 opinion. I'm going to mark this 24 as Exhibit Number 2, which is the</p>	<p>1 A. I am not a gynecologist. 2 Q. You are not an oncologist? 3 A. I am not an oncologist. 4 Q. You are not now nor have you 5 ever been licensed to practice medicine 6 in any jurisdiction? 7 A. That is correct. 8 Q. You're not a toxicologist? 9 A. That is correct. 10 Q. You're not a mineralogist? 11 A. That is correct. 12 Q. You're not a geologist? 13 A. That is correct. 14 Q. In fact, you do not have a 15 formal degree from any university in 16 epidemiology, do you? 17 A. My degree is in operations 18 research. And it might be of interest 19 that Bradford Hill's degree actually was 20 in economics. And I feel we followed 21 sort of the same career path in that our 22 jobs that we took subsequently, first of 23 all, we had the basis, the quantitative 24 basis. I had some statistics courses as</p>
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<p>1 statement that I just read. 2 BY MR. TISI: 3 Q. And you can keep that and 4 put that aside for a moment. We're going 5 to come back to that. 6 Are the bases for this 7 Ballman causation conclusion all 8 described in your epidemiology report 9 which we've marked as Exhibit Number 1? 10 A. I'm sorry. Could you repeat 11 the question? 12 Q. Yes. Are the bases for your 13 conclusion that is in Exhibit Number 2 14 all described in your report which is 15 Exhibit Number 1? 16 A. I believe that is the case. 17 I go through and support and describe the 18 methods that I used and the reasons why I 19 came to various conclusions. 20 Q. Okay. We discuss this in 21 more detail, but let me just back up for 22 a minute. 23 You're not a gynecologist, 24 true?</p>	<p>1 part of my degree. I also took some -- I 2 don't know if it was for credit or not -- 3 a seminar that was looking at sort of 4 confounding and biases in published 5 literature. And so that sort of sparked 6 my interest in statistics. And since 7 statistics was one of the tools in the 8 toolbox of operations research, my career 9 started going the direction of 10 statistics. 11 MR. TISI: Okay. I'm going 12 to move to strike. 13 BY MR. TISI: 14 Q. My question was: Do you 15 have a formal degree from any university 16 in epidemiology? 17 A. Again, I have no formal 18 degree, but I have extensive experience 19 in epidemiology and statistics through my 20 20 years of work. I mean, that's what I 21 do day in and day out. 22 Q. So the record is clear, you 23 do not have a Ph.D. in epidemiology, 24 correct?</p>

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<p>1 MS. MILLER: Objection. 2 THE WITNESS: My Ph.D. is in 3 operations research. But what I'm 4 saying is I have -- 5 BY MR. TISI: 6 Q. I understand what you're 7 saying. I need to -- 8 MS. MILLER: Please don't 9 interrupt the witness. 10 MR. TISI: No, we're going 11 to -- we're going to -- 12 MS. MILLER: No. No, you're 13 not going to interrupt her. 14 MR. TISI: We will call -- 15 no. We're going to call the 16 judge. I asked her a very 17 simple -- 18 MS. MILLER: That's fine. 19 MR. TISI: -- question. 20 MR. MILLER: That's fine if 21 you're going to call the judge -- 22 BY MR. TISI: 23 Q. Are you -- 24 MR. MILLER: -- and I'll</p>	<p>1 you do introduce yourself as a 2 statistician, correct? 3 MS. MILLER: Objection. 4 THE WITNESS: So it depends 5 what colleagues I'm introducing 6 myself to. I mean, sometimes I 7 introduce myself as a clinical 8 researcher. 9 BY MR. TISI: 10 Q. Okay. Do -- when you speak 11 to the FDA, do you introduce yourself as 12 a statistician? 13 A. When I speak to the FDA, I 14 do introduce myself as a statistician, 15 because usually, you know, it just again 16 depends upon what skills the individuals, 17 you know, are -- are in need at that 18 time. 19 But I have to say that there 20 is incredible overlap between 21 biostatistics and epidemiology. If you 22 look at any first textbook you will see 23 basically the same topics in -- whether 24 the book says epidemiology on it or</p>
Page 43	Page 45
<p>1 tell the judge that you are interrupting 2 the witness. 3 BY MR. TISI: 4 Q. Are you -- are you -- do you 5 hold a Ph.D. in -- in epidemiology? 6 MS. MILLER: Objection. 7 Asked and answered twice. 8 THE WITNESS: I do not have 9 a Ph.D. in epidemiology, but I was 10 explaining that I do have 11 extensive experience in statistics 12 and epidemiology. That's all I've 13 been doing, living and breathing 14 for the last 20 years. 15 BY MR. TISI: 16 Q. Do you have a masters degree 17 in epidemiology? 18 A. My masters degree is in 19 operations research which contains, 20 again, some statistical training and some 21 training in epidemiology. But the formal 22 degree is operations research. 23 Q. In fact, when you introduce 24 yourself to your professional colleagues,</p>	<p>1 whether the book says statistics on it. 2 And, in fact, many departments and 3 divisions across the country, like my 4 own, are departments and divisions of 5 biostatistics and epidemiology, just due 6 to the amount of overlap when it comes to 7 medical research. 8 Q. Doctor, I'm going to -- I'm 9 really going to stop and we're going to 10 call the judge. 11 I am asking you a very 12 simple, straightforward question. 13 When you introduce yourself 14 to the FDA, do you list yourself as a 15 statistician, yes or no? 16 MS. MILLER: Objection. 17 Objection. If she doesn't feel 18 like yes or no is a proper answer, 19 she needs to give you the full 20 context. 21 MR. TISI: Well, she -- I 22 will ask her -- if she needs to 23 give me full context, she can tell 24 me that and I will then ask a</p>

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<p>1 follow-up. 2 MS. MILLER: Please don't -- 3 BY MR. TISI: 4 Q. Are you -- when you 5 introduce yourself to the FDA -- 6 MS. MILLER: Please don't 7 argue with me. 8 BY MR. TISI: 9 Q. -- do you introduce yourself 10 as a statistician? 11 A. When we go around the room 12 and say -- I -- I say I -- when I 13 introduce myself around the room, when we 14 have to introduce ourselves at FDA 15 meetings, I say, usually, "I'm Karla 16 Ballman, the division chief of 17 biostatistics and epidemiology. I am a 18 statistician." 19 Q. Okay. When you apply for 20 grants for research, do you describe 21 yourself as a statistician? 22 A. I don't know if I state 23 anywhere in a grant for research as to if 24 I'm a statistician or not. It's usually</p>	<p>1 researched the causation question that 2 you are here to testify about today? 3 A. I had read some literature. 4 Q. Okay. 5 A. Did not perform formal 6 research. 7 Q. Okay. Had you ever reached 8 a conclusion about whether or not talcum 9 powder products cause ovarian cancer 10 before being retained by Ms. Sharko? 11 A. No. 12 Q. Prior to being retained by 13 Johnson &amp; Johnson lawyers to defend them 14 in lawsuits, have you ever expressed an 15 opinion one way or the other as to 16 whether or not talcum powder products are 17 capable of causing ovarian cancer? 18 MS. MILLER: Objection. She 19 wasn't retained to defend us. 20 MR. TISI: Okay. Then let 21 me rephrase the question. 22 MS. MILLER: But we're the 23 lawyers. Not -- not she. 24 BY MR. TISI:</p>
Page 47	Page 49
<p>1 investigator or co-investigator. 2 Q. Okay. Let's move to another 3 topic. 4 You know I represent women 5 who claim their use of Johnson &amp; 6 Johnson's talcum powder products caused 7 ovarian cancer, true? 8 A. I -- I don't know what you 9 do. 10 Q. Okay. When we were first -- 11 when were you first contacted by J&amp;J's 12 lawyers to consult on the question that 13 you have given your report on regarding 14 the link between ovarian cancer and 15 talcum powder products, or the lack of a 16 link? 17 MS. MILLER: Objection. 18 THE WITNESS: I was 19 contacted by Johnson &amp; Johnson 20 lawyers, I was contacted by 21 Ms. Sharko in November of 2018. 22 BY MR. TISI: 23 Q. Okay. Prior to being 24 retained by lawyers at J&amp;J, have you ever</p>	<p>1 Q. Where -- before being 2 contacted by the lawyers to be a 3 potential expert in litigation involving 4 women who claim that they may die as a 5 result of ovarian cancer caused by talcum 6 powder products, did you ever express an 7 opinion about whether or not talcum 8 powder products cause ovarian cancer? 9 MS. MILLER: Objection. 10 Your restated question was as 11 objectionable as your first 12 question. 13 THE WITNESS: And I'm sorry. 14 That was a very long question. So 15 I don't know when I answer it 16 what -- what I'm agreeing to and 17 what I'm not agreeing to, so could 18 you -- 19 BY MR. TISI: 20 Q. Prior to -- then let me 21 rephrase the question. 22 Prior to November of 2018 23 have you ever expressed an opinion as to 24 whether or not talcum powder products</p>

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<p>1 cause ovarian cancer?</p> <p>2 A. Not in any sort of formal</p> <p>3 sense. I don't know if in casual</p> <p>4 conversation someone may have said what</p> <p>5 do you think. But no, I didn't read a</p> <p>6 form -- a formal opinion.</p> <p>7 Q. Okay. Is it fair to say</p> <p>8 that the opinions that you have on the</p> <p>9 subject about whether or not talcum</p> <p>10 powder products cause ovarian cancer</p> <p>11 occurred after you've spoke to the</p> <p>12 lawyers for the first time in November of</p> <p>13 2018?</p> <p>14 MS. MILLER: Objection.</p> <p>15 THE WITNESS: So my opinion</p> <p>16 as to whether or not there is</p> <p>17 evidence that talcum powder causes</p> <p>18 ovarian cancer, is based upon the</p> <p>19 research that I had done.</p> <p>20 I -- I did not reach a</p> <p>21 formal opinion until I had done</p> <p>22 the research and looked at the</p> <p>23 data in totality.</p> <p>24 BY MR. TISI:</p>	<p>1 BY MR. TISI:</p> <p>2 Q. And that would have been</p> <p>3 after you met with the lawyers for</p> <p>4 Johnson &amp; Johnson, correct?</p> <p>5 A. I was --</p> <p>6 MS. MILLER: Objection.</p> <p>7 Please remember to give me</p> <p>8 time to object.</p> <p>9 THE WITNESS: I did not</p> <p>10 start the research until after</p> <p>11 November 2018.</p> <p>12 BY MR. TISI:</p> <p>13 Q. When you first met the</p> <p>14 Johnson &amp; Johnson lawyers?</p> <p>15 MS. MILLER: Objection.</p> <p>16 THE WITNESS: Again, I had</p> <p>17 no reason to do any research</p> <p>18 before that, and so I started the</p> <p>19 research after I was retained to</p> <p>20 do -- to render an opinion.</p> <p>21 BY MR. TISI:</p> <p>22 Q. Now, is it fair to say that</p> <p>23 you never published on the subject of</p> <p>24 talcum powder and ovarian cancer?</p>
Page 51	Page 53
<p>1 Q. And that was after November</p> <p>2 of 2018?</p> <p>3 A. Well, I -- I -- that's when</p> <p>4 I started the research --</p> <p>5 Q. Right.</p> <p>6 A. -- on -- on the issue.</p> <p>7 Q. So the answer to my question</p> <p>8 is, the first time you ever reached a</p> <p>9 conclusion based upon your evaluation of</p> <p>10 the data did not occur until after you</p> <p>11 first met with Ms. Sharko in 2018 --</p> <p>12 MS. MILLER: Object.</p> <p>13 BY MR. TISI:</p> <p>14 Q. -- November?</p> <p>15 MS. MILLER: Objection.</p> <p>16 THE WITNESS: So -- so how I</p> <p>17 would say it is I did not start</p> <p>18 doing research on the issue until</p> <p>19 after November of 2018. And as a</p> <p>20 result of that research, I reached</p> <p>21 a conclusion which obviously,</p> <p>22 since I didn't start the research</p> <p>23 until November, I didn't reach the</p> <p>24 conclusion until after November.</p>	<p>1 A. That is correct. There are</p> <p>2 no publications with my name on it.</p> <p>3 Q. And though you have by my</p> <p>4 count over 200 publications in the</p> <p>5 literature, you didn't cite any of your</p> <p>6 own literature for -- or any of your</p> <p>7 published work in your report, correct?</p> <p>8 A. I again just used the</p> <p>9 research tools that I use when I do any</p> <p>10 sort of research. And, you know, there</p> <p>11 are many publications, as you see, that I</p> <p>12 have there where I cite none of my own</p> <p>13 work. I just use what's relevant to</p> <p>14 doing the research for the question at</p> <p>15 hand.</p> <p>16 Q. And your work was not</p> <p>17 relevant to your report, correct?</p> <p>18 MS. MILLER: Objection.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Or you would have cited it?</p> <p>21 MS. MILLER: Objection.</p> <p>22 THE WITNESS: So my</p> <p>23 experience is extremely relevant</p> <p>24 to my opinion, and my work is my</p>

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<p>1 experience. And so --</p> <p>2 BY MR. TISI:</p> <p>3 Q. Okay. But your published</p> <p>4 research, you did not rely on any of your</p> <p>5 published research in crafting your</p> <p>6 report because it's not -- it's not in</p> <p>7 the bibliography or the -- anything</p> <p>8 relied on that was given to us, so I'll</p> <p>9 represent to you that I looked through</p> <p>10 all -- all of your citations, and there's</p> <p>11 not a single reference to any of your</p> <p>12 published work. Is that accurate?</p> <p>13 MS. MILLER: Objection.</p> <p>14 THE WITNESS: So there are</p> <p>15 no references --</p> <p>16 BY MR. TISI:</p> <p>17 Q. Okay.</p> <p>18 A. -- to my own published work.</p> <p>19 But that wasn't necessary -- in my --</p> <p>20 that -- because it was based upon my</p> <p>21 experience and I used what were the</p> <p>22 relevant pieces of the epidemiology and</p> <p>23 actually, you know, the reports that I</p> <p>24 read, and that is in my report.</p>	<p>1 A. Yes. I do reference this</p> <p>2 article.</p> <p>3 Q. Okay. Since 1982, you would</p> <p>4 agree with me that there are over 30</p> <p>5 epidemiologic studies that have been</p> <p>6 published?</p> <p>7 A. Since this time, I believe</p> <p>8 the studies that I have in my report and</p> <p>9 I reviewed included a total of about 30</p> <p>10 that were case-control studies or cohort</p> <p>11 studies, and meta-analyses.</p> <p>12 Q. Right. So between 1982 and</p> <p>13 the time that we sit here today in 2019,</p> <p>14 there are over 30 studies, and these</p> <p>15 include population-based case-control</p> <p>16 studies, correct?</p> <p>17 A. There are population-based</p> <p>18 case-control studies.</p> <p>19 Q. They include hospital-based</p> <p>20 case-control studies, right?</p> <p>21 A. There are hospital-based</p> <p>22 case-control studies.</p> <p>23 Q. Cohort studies, which you</p> <p>24 mentioned.</p>
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<p>1 Q. Okay. And you know that the</p> <p>2 first epidemiologic study that described</p> <p>3 the potential association between talcum</p> <p>4 powder products and ovarian cancer was</p> <p>5 published by researchers out of Harvard</p> <p>6 University in 1982, correct?</p> <p>7 MS. MILLER: Objection.</p> <p>8 THE WITNESS: So it -- I</p> <p>9 don't know with complete</p> <p>10 confidence, but I do know that the</p> <p>11 first publication that I reviewed</p> <p>12 that had an association in it, I</p> <p>13 believe was in 1982 by Cramer.</p> <p>14 BY MR. TISI:</p> <p>15 Q. Okay. I'm just going to,</p> <p>16 for purposes of the record, I will attach</p> <p>17 the Cramer article as Exhibit Number 3.</p> <p>18 (Document marked for</p> <p>19 identification as Exhibit</p> <p>20 Ballman-3.)</p> <p>21 BY MR. TISI:</p> <p>22 Q. Is that the same -- Exhibit</p> <p>23 Number 3 the Cramer article that you</p> <p>24 referenced?</p>	<p>1 A. There are cohort studies.</p> <p>2 Q. Meta-analyses of the</p> <p>3 epidemiologic studies?</p> <p>4 A. There are meta-analyses of</p> <p>5 the observational studies.</p> <p>6 Q. A pooled analysis?</p> <p>7 A. There is a pooled analysis.</p> <p>8 Q. And there are biologic</p> <p>9 studies, which you also refer to?</p> <p>10 A. There are -- there are some</p> <p>11 biological studies.</p> <p>12 Q. Okay. And of all those</p> <p>13 studies in the past 40 years, you have</p> <p>14 not been involved in any of them, your</p> <p>15 name doesn't appear in any of those</p> <p>16 studies, correct?</p> <p>17 A. I am not an author on any of</p> <p>18 those studies that you cited.</p> <p>19 Q. Well, you were not involved</p> <p>20 in any way in any of those studies,</p> <p>21 correct, because your involvement in</p> <p>22 this -- this issue didn't really happen</p> <p>23 until after November of 2018, correct?</p> <p>24 A. So involvement, I'm not sure</p>

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<p style="text-align: right;">Page 58</p> <p>1 how to quite interpret that. I mean, I 2 have vast amount of experience of 3 analyzing data that are in these types of 4 studies -- 5 MS. MILLER: Please don't 6 interrupt her. 7 THE WITNESS: -- in terms of 8 coming to a conclusion. 9 BY MR. TISI: 10 Q. Doctor, I'm not asking you 11 what your background is now. I'm asking 12 you prior to November of 2018, had you 13 ever been involved in any study, 14 observational or otherwise, in any 15 capacity involving talcum and ovarian 16 cancer? 17 A. I have no publications in 18 talc and ovarian cancer. 19 Q. I'm not limiting it to 20 publications. I'm asking you, had you 21 had any involvement in any fashion with 22 any study involving ovarian cancer and 23 talc? 24 A. So again, I'm not sure what</p>	<p style="text-align: right;">Page 60</p> <p>1 for over 40 years. You've seen -- you've 2 seen articles across the spectrum, 3 correct? 4 MR. LOCKE: Objection. 5 MS. MILLER: Objection. 6 That's like seven different 7 questions all in one. 8 MR. TISI: Yes. 9 BY MR. TISI: 10 Q. There are multiple 11 scientists -- let me rephrase the 12 question. 13 There are multiple 14 scientists from multiple disciplines that 15 have looked at the questions related to 16 ovarian cancer and talc for over 17 40 years, true? 18 MS. MILLER: Objection. 19 THE WITNESS: So I don't 20 know what you mean by "multiple." 21 But when there's any sort of topic 22 that's researched, it involves, 23 you know, many different people. 24 It's never -- I mean, it's not</p>
<p style="text-align: right;">Page 59</p> <p>1 you mean by the term "involvement." I 2 mean -- 3 Q. Did anyone -- then I'll 4 rephrase it. Okay. 5 Did anyone ever call you and 6 say, "You know, we're doing a study, 7 Dr. Ballman. Can you give us your 8 informal advice on how to design it," 9 involving ovarian cancer -- 10 MS. MILLER: Objection. 11 BY MR. TISI: 12 Q. -- and talcum powder 13 products? 14 MS. MILLER: Objection. 15 THE WITNESS: I have not 16 received such a phone call. 17 BY MR. TISI: 18 Q. Okay. And would you agree 19 with me that there are literally dozens 20 of scientists that have been involved in 21 this issue over 40 years, involved in the 22 epidemiology studies, toxicologists, 23 pharmacologists, mineralogist, have been 24 involved in the ovarian cancer talc issue</p>	<p style="text-align: right;">Page 61</p> <p>1 valuable research if it's just one 2 person. So I don't think talcum 3 powder and ovarian cancer is any 4 different from any other research 5 field that you had mentioned. 6 BY MR. TISI: 7 Q. Right. And so the answer to 8 the question is there are literally 9 dozens of scientists across the spectrum 10 that have been looking at these issues 11 and publishing in this area for 40 years, 12 true? 13 MS. MILLER: Objection. 14 THE WITNESS: I can't answer 15 that with certainty. I don't know 16 how many scientists. I don't know 17 how long it's been -- 18 BY MR. TISI: 19 Q. There are many. How about 20 many? 21 A. Just like any other research 22 topic, it's -- it's what one would 23 expect, yes. 24 Q. Okay. Have any of them been</p>

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<p>1 you?</p> <p>2 MS. MILLER: Objection.</p> <p>3 We've been through this.</p> <p>4 THE WITNESS: You know, I --</p> <p>5 I have not done myself a study in</p> <p>6 ovarian cancer, a published study</p> <p>7 in ovarian cancer and talc. I</p> <p>8 have done research on this topic</p> <p>9 as we talked about after</p> <p>10 November 2018 --</p> <p>11 BY MR. TISI:</p> <p>12 Q. Okay.</p> <p>13 A. -- using all the expertise I</p> <p>14 have in similar types of studies that</p> <p>15 I've been involved in, but just didn't</p> <p>16 have the topic ovarian cancer and talcum</p> <p>17 powder.</p> <p>18 Q. Now, I can represent to you</p> <p>19 that Johnson &amp; Johnson has produced, as</p> <p>20 they tell me all the time, millions of</p> <p>21 pages of documents in connection with</p> <p>22 this litigation. And I'll represent that</p> <p>23 to you. And that covers the time span</p> <p>24 since the 1960s and perhaps even before.</p>	<p>1 MS. MILLER: Objection.</p> <p>2 Asked and answered.</p> <p>3 THE WITNESS: Yeah, again, I</p> <p>4 just don't know why -- why a</p> <p>5 company -- I -- I don't know how</p> <p>6 companies operate. I don't know</p> <p>7 if they engage experts to do</p> <p>8 research for them necessarily.</p> <p>9 I mean, some companies may</p> <p>10 and some companies may not, I just</p> <p>11 don't know.</p> <p>12 BY MR. TISI:</p> <p>13 Q. Johnson &amp; Johnson never</p> <p>14 contacted you in 40 years to ever perform</p> <p>15 a study or advise them in any fashion</p> <p>16 about either how to design a study to</p> <p>17 look at the question of ovarian cancer,</p> <p>18 did they?</p> <p>19 A. I --</p> <p>20 MS. MILLER: Objection.</p> <p>21 Please give me ten seconds.</p> <p>22 THE WITNESS: I know it.</p> <p>23 I'm so sorry.</p> <p>24 MS. MILLER: That's all it</p>
Page 63	Page 65
<p>1 Would it surprise you that</p> <p>2 your name, Karla Ballman, isn't mentioned</p> <p>3 as having been contacted even once by</p> <p>4 Johnson &amp; Johnson on the issue of ovarian</p> <p>5 cancer and talcum powder products in that</p> <p>6 whole time?</p> <p>7 MS. MILLER: Objection.</p> <p>8 THE WITNESS: I wouldn't --</p> <p>9 I'm -- don't even know how to</p> <p>10 answer that.</p> <p>11 I -- I wouldn't know why a</p> <p>12 company would contact me or have</p> <p>13 my name in any sort of documents</p> <p>14 that -- that they generated if I</p> <p>15 hadn't been working with the</p> <p>16 company. I just don't know how to</p> <p>17 answer that.</p> <p>18 BY MR. TISI:</p> <p>19 Q. Would it surprise you that</p> <p>20 there's no -- nobody ever mentioned we</p> <p>21 need to contact Karla Ballman and obtain</p> <p>22 her expertise about whether or not talcum</p> <p>23 powder product caused ovarian cancer in</p> <p>24 that 40-year period?</p>	<p>1 takes.</p> <p>2 THE WITNESS: Again, I'm</p> <p>3 just at a loss. I don't know why</p> <p>4 they would.</p> <p>5 BY MR. TISI:</p> <p>6 Q. Okay. Well --</p> <p>7 A. Because again, I don't know</p> <p>8 if they do research. I don't know if</p> <p>9 they contact people to do research from</p> <p>10 them for them, so I -- I just don't --</p> <p>11 Q. Well, I'll represent to you</p> <p>12 that they have. Okay.</p> <p>13 Among other people they've</p> <p>14 contacted, do you know who Ken Rothman</p> <p>15 is?</p> <p>16 A. No.</p> <p>17 Q. You don't know -- you</p> <p>18 testified in your Viagra litigation that</p> <p>19 you knew who Ken Rothman was. He's an</p> <p>20 epidemiologist who published a textbook</p> <p>21 on epidemiology.</p> <p>22 A. Oh, yeah.</p> <p>23 Q. Do you remember that?</p> <p>24 A. Yeah, yeah, yeah, yeah,</p>

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<p>1 yeah. I don't know him personally. 2 Q. Right. But he is a -- he is 3 a well-established epidemiologist, 4 correct? 5 MS. MILLER: Objection. 6 THE WITNESS: He is an 7 epidemiologist and I've heard his 8 name. 9 BY MR. TISI: 10 Q. Right. And you also -- 11 and -- contacted Drs. Huncharek and 12 Muscat. You've seen those names, 13 correct? 14 A. I have seen those names. 15 Q. Okay. And I'm going to tell 16 you, over the course of 40 years, they 17 have contacted people from various 18 disciplines to -- for various questions 19 related to talc and ovarian cancer. I 20 want to ask you to assume that that is 21 true. And I will -- 22 MS. MILLER: Objection. 23 MR. TISI: I haven't even 24 asked the question, counsel.</p>	<p>1 it's unusual. I'm just asking you the 2 simple question. They never -- none of 3 the lawyers -- excuse me. 4 None of the scientists at 5 Johnson &amp; Johnson ever contacted you over 6 the past 40 years to seek your advice, 7 true? 8 A. I have not been -- 9 MS. MILLER: Objection. 10 THE WITNESS: Oh, sorry. 11 BY MR. TISI: 12 Q. You may answer. 13 A. Yeah. 14 Q. She is going to object to 15 everything, so just -- 16 A. I'll wait, I need to wait. 17 MS. MILLER: I'm not going 18 to object if you don't ask 19 objectionable questions. 20 MR. TISI: Okay. 21 MS. MILLER: It's a simple 22 solution. 23 THE WITNESS: I have not 24 been contacted by anyone in</p>
Page 67	Page 69
<p>1 MS. MILLER: I didn't even 2 know. I can't tell what's a 3 question and what's a lecture. 4 MR. TISI: Well, then 5 wait -- wait till the end. 6 BY MR. TISI: 7 Q. At no time did any scientist 8 or regulatory person from Johnson &amp; 9 Johnson ever contact Dr. Ballman to ask 10 her opinions until the lawyers contacted 11 you in November of 2018, would that be a 12 true statement? 13 MS. MILLER: Objection. 14 THE WITNESS: Again, as I 15 said, I -- I just don't know how 16 companies operate. You tell me 17 they've had -- they hire experts 18 and I have no evidence one way or 19 another if they do. 20 But I had not been contacted 21 by Johnson &amp; Johnson, but I don't 22 know if that's unusual. I just -- 23 BY MR. TISI: 24 Q. I'm not asking you whether</p>	<p>1 Johnson &amp; Johnson. 2 BY MR. TISI: 3 Q. Related to the issue of 4 talcum powder products and ovarian 5 cancer, true? 6 A. If you don't count the 7 lawyers, and I'm not sure what that 8 relationship means, I -- I have not. 9 Q. Okay. Would it surprise you 10 that when we looked in the Johnson -- in 11 the millions of pages of documents that 12 Johnson &amp; Johnson sent to us, that not a 13 single article of research that you have 14 ever done has appeared in -- in any 15 bibliography for any issue related to 16 ovarian cancer, would that surprise you? 17 MS. MILLER: Objection. 18 THE WITNESS: You know, 19 again, I don't know what documents 20 or what's in those million pages. 21 So I don't know if that would 22 surprise me or not. 23 BY MR. TISI: 24 Q. Well, can you think of any</p>

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<p>1 article that you've ever written that 2 would be relevant to the question of 3 whether or not ovarian cancer is caused 4 by talcum powder products? 5 MS. MILLER: Objection. 6 THE WITNESS: Well, I have 7 expertise in other -- in -- in 8 just sort of this type of thing in 9 general. But if -- if it's 10 related to ovarian cancer and 11 talcum powder as we discussed, 12 there would not be any 13 publications with my name on it 14 that -- that address ovarian 15 cancer and talcum powder. 16 BY MR. TISI: 17 Q. Now, even as of today, we're 18 now in March of 2019, since Ms. Sharko 19 found you as an expert witness in this 20 litigation, have you ever been in contact 21 with any J&amp;J scientist that -- where they 22 said well, now that we found you, 23 Dr. Ballman, maybe you can help us design 24 a study or give us your advice on</p>	<p>1 Q. Okay. And that would be for 2 research, correct? 3 A. I haven't been contacted by 4 anyone in Johnson &amp; Johnson. 5 Q. And that would be to help 6 them in any regulatory issue, correct? 7 A. I have not been contacted by 8 anyone in Johnson &amp; Johnson. 9 Q. Okay. So it's the 10 company -- and I'm distinction the 11 company from the lawyers. 12 The company has not spent 13 any time and effort trying to understand 14 your opinions or the basis of it, just 15 the lawyers, true? 16 MS. MILLER: Objection. 17 THE WITNESS: Again, I'm not 18 sure how to answer that because I 19 was retained in terms of the 20 litigation. I don't know if 21 there's any rules that surround 22 that or whatever. I have no idea. 23 BY MR. TISI: 24 Q. But the answer would be no,</p>
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<p>1 causation or any -- anything related to 2 talcum powder products and ovarian 3 cancer, have you spoken to any scientist 4 at J&amp;J since November of 2018? 5 A. I have not spoke -- 6 MS. MILLER: You've got to 7 let me object. There was like, 8 seven questions in there. You've 9 got to give me time to object. 10 That was objectionable. 11 THE WITNESS: Can you 12 rephrase? Not rephrase. Just 13 repeat. 14 BY MR. TISI: 15 Q. Since you've been found as 16 an expert witness in November of 2018, 17 has any scientist at Johnson &amp; Johnson 18 reached out to you to ask your opinion on 19 talcum powder products and ovarian 20 cancer? 21 A. Since I have been retained 22 by the lawyer -- by Johnson &amp; Johnson in 23 2018 for this case, I have not been 24 contacted by anyone in Johnson &amp; Johnson.</p>	<p>1 you've not been retained and spoken to 2 anybody at Johnson &amp; Johnson in 3 connection with any scientific question 4 outside of the legal arena, correct? 5 A. As I mentioned, I have not, 6 as far as I know, talked to anyone from 7 Johnson &amp; Johnson. 8 Q. In fact, Johnson &amp; Johnson 9 makes hundreds of products for 10 pharmaceuticals, medical devices and 11 cosmetics. You know that to be true, 12 correct? 13 MS. MILLER: Objection. 14 THE WITNESS: I know they 15 make lots of products. I don't 16 know how many. I don't know what 17 the span is of the different 18 areas. 19 BY MR. TISI: 20 Q. Has any Johnson &amp; Johnson 21 scientist ever reached out to you to help 22 them understand any scientific question 23 for any reason? 24 MS. MILLER: Objection.</p>

19 (Pages 70 to 73)



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<p style="text-align: right;">Page 74</p> <p>1 THE WITNESS: Again, I don't 2 know how companies operate. I 3 don't know -- I mean I presume 4 they have their own scientists. 5 I'm not sure if they are reaching 6 out. I just -- 7 BY MR. TISI: 8 Q. I'm asking you what they did 9 for you. And I am not asking you to get 10 in their mind and figure out what their 11 policies are or anything like that. 12 Has Johnson &amp; Johnson, any 13 Johnson &amp; Johnson scientist ever reached 14 out to Dr. Karla Ballman to ask her help 15 in understanding any scientific question 16 for any reason? 17 A. Again, I have not talked to 18 anyone in an official capacity from 19 Johnson &amp; Johnson. 20 Q. And you have a career 21 spanning how many decades now? 22 A. Oh, easily about two to 23 three decades. 24 Q. Okay. And in that two or</p>	<p style="text-align: right;">Page 76</p> <p>1 A. I believe -- myself, or just 2 the institution I work for? 3 Q. Your team. You and your -- 4 anybody that you may collaborate with? 5 A. There might have been one or 6 two occasions. 7 Q. Okay. But they've not been 8 Johnson &amp; Johnson? 9 A. That is correct. 10 Q. Johnson &amp; Johnson never 11 asked you to represent them on any issue 12 before the FDA related to talcum powder 13 products, have they? 14 MS. MILLER: Objection. 15 THE WITNESS: I have not 16 been before the FDA on behalf of 17 Johnson &amp; Johnson. 18 BY MR. TISI: 19 Q. For any reason including -- 20 A. For any reason. 21 Q. Okay. You know that IARC 22 looked at the question of ovarian cancer 23 and talcum powder products in 2006 24 correct?</p>
<p style="text-align: right;">Page 75</p> <p>1 three decades, no one from Johnson &amp; 2 Johnson ever reached out to you and asked 3 you, "Hey, you know, we got this problem 4 here. Can you help us design a study or 5 analyze data, perform a causation 6 analysis," anything scientist related? 7 MS. MILLER: Objection. 8 THE WITNESS: So I am in 9 academia. So, you know, I don't 10 know why they would necessarily 11 reach out to me in particular. No 12 other companies do either. 13 BY MR. TISI: 14 Q. You've never done studies 15 for any company? 16 A. I didn't say that. 17 Q. Okay. You've done studies 18 for companies, true? You've done studies 19 that have been sponsored by companies, 20 correct? 21 A. So now you'll have to 22 define -- 23 Q. Have you received funding 24 from companies to do studies?</p>	<p style="text-align: right;">Page 77</p> <p>1 A. I read a report from IRAC 2 (sic) who -- that looked at that 3 question. 4 Q. And were you asked by 5 anybody in the talc industry to help them 6 understand that talc-ovarian-cancer 7 connection in connection with the IARC 8 proceedings in 2006? 9 A. I was not part of the IRAC 10 (sic) committee that looked at that 11 question. 12 Q. You say IRAC. Is it IRAC 13 or -- 14 A. I'm sorry. IARC. I know. 15 I did that -- I do that often. 16 Q. That's okay. I do it too. 17 A. It's IARC. 18 Q. Okay. And what does IARC 19 stand for? 20 A. International Agency -- I 21 don't remember the title. I can get it. 22 Q. Did J&amp;J scientists -- 23 MS. MILLER: Wait. She's 24 looking for the answer.</p>

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<p>1 MR. TISI: Actually, that's 2 fine. 3 MS. MILLER: Are you 4 striking the question? 5 MR. TISI: No, I just -- 6 it's fine. 7 MS. MILLER: If you're not 8 striking the question -- 9 MR. TISI: She didn't 10 know -- she didn't know the 11 answer. 12 MS. MILLER: Well, she's 13 checking her report and she'd like 14 to finish answering. 15 BY MR. TISI: 16 Q. Do you know without looking 17 in your report, Doctor? 18 A. I am not very good at all 19 acronyms and stuff. 20 Q. Okay. 21 A. And as you see I don't even 22 pronounce them correctly because I get 23 the letters mixed up. So I want to be 24 correct when I say what the title is</p>	<p>1 they someone that you come in contact 2 with through the literature and your 3 understanding of the -- of cancer and 4 cancer research? 5 MS. MILLER: Objection. 6 That was two questions. 7 THE WITNESS: Again, as I 8 said, I mean, IARC is an 9 established committee that people 10 know do research on cancer to 11 determine whether or not there is 12 carcinogenic risk to humans and 13 people refer to them, as I do 14 myself. 15 BY MR. TISI: 16 Q. And are they -- when you say 17 refer to them, they rely on them, 18 correct? 19 MS. MILLER: Objection. 20 THE WITNESS: I'm not sure 21 what you mean rely on them. 22 BY MR. TISI: 23 Q. You go -- 24 A. I mean, they go -- I go -- I</p>
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<p>1 of -- of that agency. 2 And it's right here 3 somewhere. International Agency For 4 Research on Cancer. 5 Q. Have you ever been asked by 6 can IARC to participate in any 7 deliberation about whether or not a 8 substance causes cancer? 9 A. I have not been on any IARC 10 committee. 11 Q. Has IARC a well respected 12 scientific organization? 13 MS. MILLER: Objection. 14 THE WITNESS: I believe IARC 15 gets experts in the areas that 16 they need to adjust -- to address 17 the questions that come before 18 them or that they deem of 19 interest. 20 BY MR. TISI: 21 Q. Do you -- 22 A. That's all I know. 23 Q. Do you consider them a well 24 respected scientific organization? Are</p>	<p>1 look at them to see what -- what their 2 evidence is and what their conclusions 3 are. 4 Q. Okay. Are they considered 5 to be a respectable scientific 6 organization? 7 MS. MILLER: Objection. 8 THE WITNESS: They -- again, 9 they are an organization. I mean, 10 it depends upon what you mean by 11 respectable. I mean, as I said 12 they're well established. I use 13 them as a reference. Many other 14 people use them as references. 15 BY MR. TISI: 16 Q. Okay. Now, this IARC report 17 that you refer to in your report was 18 issued in 2010. But you do understand 19 that IARC looked at evidence before 2006, 20 correct? It was published in 2010, but 21 the conclusions were reached as of 2006. 22 Do you understand that to be true? 23 MS. MILLER: Objection. 24 THE WITNESS: I -- I believe</p>

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<p>1 I'd have to look at the dates to 2 make sure. But I -- I do agree 3 that the actual monograph came out 4 after they had done analyses and 5 the data that they use for that 6 analyses. 7 BY MR. TISI: 8 Q. Now, you do know that in 9 December 2018, two months before you 10 issued your litigation report for J&amp;J's 11 lawyers, Health Canada looked at the 12 question as to whether or not, in your 13 words, the epidemiology studies and 14 scientific literature supported a causal 15 relationship between talcum powder 16 products and ovarian cancer. 17 Do you -- do you know that 18 to be true? 19 MS. MILLER: Objection. 20 THE WITNESS: So are you 21 asking me if I'm aware that Health 22 Canada has issued a -- could -- 23 could you rephrase that? 24 BY MR. TISI:</p>	<p>1 time that you wrote your report? 2 A. I -- I actually looked it up 3 before -- as I was writing my report, 4 before it was finalized. 5 Q. Okay. So you were familiar 6 with it, but didn't list it in your 7 report as something that you had 8 considered in connection with your 9 opinions? 10 A. I did not reference it. 11 And -- and actually, I may have 12 misspoken. I -- it's been such a blur 13 these last two year -- months -- I 14 don't -- even years, it feels like years. 15 I -- I'm not sure exactly 16 when I looked at what, so -- but I do 17 believe I did see it before I finalized 18 my report, because I do reference the 19 Taher meta-analysis. 20 Q. Right. Well, you know the 21 Taher meta-analysis was commissioned by 22 Health Canada and then used in the Health 23 Canada report, you know that they are two 24 separate reports?</p>
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<p>1 Q. Yes. Yes. Do you know that 2 in December 2018 they issued a, call it a 3 draft report, about assessing the various 4 lines of evidence using the Bradford Hill 5 criteria on the question about whether or 6 not talcum powder products is capable of 7 causing ovarian cancer? 8 A. I know that Health Canada 9 has issued -- did issue a draft report 10 late last year. 11 Q. Okay. And you know that 12 they looked at the evidence through the 13 Bradford Hill criteria, correct? 14 MS. MILLER: Objection. 15 THE WITNESS: I -- can 16 you -- can I see the report, 17 please? I can't -- 18 BY MR. TISI: 19 Q. I will give it -- I will 20 give it to you. But you -- it was 21 provided to you. I saw it on your 22 supplemental reliance list that was 23 turned over to us last night. 24 Did you have that at the</p>	<p>1 A. They are two separate 2 reports. 3 Q. Okay. Now, Health Canada, 4 just for the record, is the Canadian 5 equivalent to the U.S. FDA? 6 A. That -- 7 MS. MILLER: Objection. 8 THE WITNESS: That's what 9 I've been told. I -- I don't 10 know. I didn't know one way or 11 the other. 12 BY MR. TISI: 13 Q. And other than for 14 litigation purposes, and I mean on both 15 sides, plaintiffs' experts and 16 defendants' experts, are you aware of any 17 more recent analysis of the causation 18 question through a Bradford Hill 19 framework than the one conducted by 20 Health Canada outside of litigation, are 21 you aware of anything else? 22 A. That's a long question. Do 23 you want to do -- I mean, I don't know -- 24 Q. Let me -- let me --</p>

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<p>1 A. -- because you're putting 2 Bradford Hill in there and -- 3 Q. Let me rephrase the question 4 then. 5 Do you know of any authors, 6 published or unpublished, apart from 7 litigation, which has done a causation 8 analysis of the question of ovarian 9 cancer and talc more recently than Health 10 Canada in December of 2018? 11 A. So the Health Canada report, 12 you mean, unpublished report, draft 13 report? 14 Q. Correct. 15 A. Has there been another 16 published study? 17 Q. Has there been any other 18 published or unpublished analysis of the 19 question of about whether ovarian cancer 20 and talcum powder products are linked, 21 is -- is that the most recent, outside of 22 litigation, that you can think of? 23 A. Oh, out -- 24 MS. MILLER: Objection.</p>	<p>1 BY MR. TISI: 2 Q. And in your -- in your 3 practice of -- in your professional 4 practice outside of litigation, is it 5 important for you to consider the 6 opinions and views of other scientists 7 who look at the same or similar questions 8 that you were asked to look at? 9 A. That's a really broad 10 question. 11 Q. Do you consider the views of 12 other scientists? 13 MS. MILLER: Objection. 14 THE WITNESS: When I do 15 research, I -- I look at 16 publications. So I believe those 17 probably are views of -- of other 18 scientists. I mean, to do 19 research, you -- you need to look 20 at the literature. 21 BY MR. TISI: 22 Q. Do you speak -- do you speak 23 to colleagues and get their opinions? 24 A. If we're doing research in</p>
Page 87	Page 89
<p>1 THE WITNESS: Outside of 2 litigation? I -- I don't know off 3 the top of my head. I'd have to 4 go through and look at all the 5 reports. 6 BY MR. TISI: 7 Q. Okay. Okay. I'm going to 8 have marked as Exhibit 4 a document which 9 is the draft screening assessment from 10 Health Canada. 11 Now, this is on the 12 supplemental reliance list that was 13 served on us last night, correct? 14 A. I -- 15 MS. MILLER: I don't think 16 she knows when it was served. 17 BY MR. TISI: 18 Q. Okay. Well -- all right. 19 You've seen this, correct? 20 A. I have seen this, correct. 21 Q. Okay. 22 (Document marked for 23 identification as Exhibit 24 Ballman-4.)</p>	<p>1 the same area, I may speak to a colleague 2 with respect to a research question I'm 3 working on. 4 Q. Do you go to meetings where 5 information is presented orally or on 6 posters? 7 A. I go to many meetings, and 8 so often there are information presented 9 orally and on posters. 10 Q. And on -- on the whole, the 11 views of other scientists is information 12 that you integrate into your knowledge 13 base when you look at scientific 14 questions, true? 15 MS. MILLER: Objection. 16 THE WITNESS: So it all 17 depends. It depends upon the 18 quality of -- of the data. I look 19 at the data. I -- I -- you know, 20 determine whether or not the 21 conclusions that they reach is -- 22 is justified by the data that they 23 have and their study design. And 24 so, I -- I -- you know, just</p>

23 (Pages 86 to 89)

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<p style="text-align: right;">Page 90</p> <p>1 because it's another scientist 2 doesn't necessarily mean... 3 BY MR. TISI: 4 Q. Now -- 5 MS. MILLER: We've been 6 going about an hour. Is this a 7 good time for a break or? 8 MR. TISI: Actually let me 9 finish this -- this area here. 10 BY MR. TISI: 11 Q. In -- the other report, I'm 12 going to talk about, you were involved in 13 the Viagra/Cialis litigation? 14 A. Yes. 15 Q. Okay. And you issued a 16 report in that litigation as well? 17 A. I did. 18 Q. You had a section in that 19 report dealing with regulatory issues and 20 the regulatory views of various European 21 and -- and U.S. agencies. Do you recall 22 that? 23 A. Can I see it, please? 24 Q. I don't have it with me,</p>	<p style="text-align: right;">Page 92</p> <p>1 Do you see that? 2 MS. MILLER: Objection. 3 It's not a study. It's a table. 4 BY MR. TISI: 5 Q. Do you see that? 6 A. I see a table that's titled 7 "Available Human Epidemiological Studies 8 Investigating the Association of Perineal 9 Talc and Ovarian Cancer." 10 Q. And as you glance through 11 these, the studies that are listed here, 12 these are studies that are familiar to 13 you, correct? 14 A. These look like they include 15 some of the case-control studies and 16 cohort studies that have been used in 17 other meta-analyses. 18 Q. Okay. They cover -- for 19 example, I see the Cramer study from 1982 20 that we marked? 21 A. I see that. 22 Q. Okay. And they cover 23 case-control studies, population-based 24 and hospital-based studies.</p>
<p style="text-align: right;">Page 91</p> <p>1 but -- but do you recall that, I'm asking 2 whether you recall -- 3 MS. MILLER: Objection. 4 THE WITNESS: No, I -- I 5 don't recall any specifics. 6 BY MR. TISI: 7 Q. Okay. 8 MS. MILLER: Give me time to 9 object, please. 10 Objection. 11 THE WITNESS: So, sorry. 12 BY MR. TISI: 13 Q. Let me ask you this. Go to 14 Page 16 -- 15 MS. MILLER: Of what? 16 MR. TISI: Of Exhibit 4. 17 BY MR. TISI: 18 Q. There's a Table 6.1. Do you 19 see that? 20 A. I do see the table. 21 Q. And it's a study entitled 22 "Available human epidemiologic studies 23 investigating the association of perineal 24 talc use and ovarian cancer."</p>	<p style="text-align: right;">Page 93</p> <p>1 Do you see that? 2 A. I see that study type is 3 listed. I don't know which are hospital 4 based and which are population based. 5 Q. And if -- if you look on 6 Page 18, it includes the cohort studies. 7 Do you see that? 8 A. Yes. I see page 18 lists 9 cohort studies. 10 Q. And they considered the 11 meta-analyses that you also looked at. 12 If you look at Page 16 under human 13 studies. It has the sentence, "Several 14 meta-analyses are available of the 15 epidemiologic data have been published, 16 some very recently. (Huncharek, 2003; 17 Langseth, 2008; Terry, 2018; Berge, 2018, 18 Penninkilampi and Eslick, 2018; Taher, 19 2018)." 20 Do you see that those? 21 A. I see that. I didn't 22 realize that Taher has been published. 23 Q. It's -- it's not been 24 published yet.</p>

24 (Pages 90 to 93)



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<p>1 A. But it says published.</p> <p>2 Q. Okay. So let me ask you</p> <p>3 this. Those are all studies that you're</p> <p>4 familiar with, correct? You've seen</p> <p>5 those?</p> <p>6 A. I have seen those studies.</p> <p>7 Q. All right. And so does it</p> <p>8 appear from looking at the studies, they</p> <p>9 considered pretty much -- they considered</p> <p>10 the same studies that you considered?</p> <p>11 A. I -- I -- I mean, I'd have</p> <p>12 to go through and look and compare</p> <p>13 whether or not every single study here is</p> <p>14 what every single study that I looked at.</p> <p>15 But I do -- it appears that, you know, I</p> <p>16 recognize the names of many of these</p> <p>17 studies here. I don't know if it's a</p> <p>18 complete match.</p> <p>19 Q. Okay. Now, can you turn to</p> <p>20 Page 19 through 21. On the very bottom</p> <p>21 of the page on 19 it has a section called</p> <p>22 "Strength"?</p> <p>23 A. Yes, I see that.</p> <p>24 Q. That's one of the Bradford</p>	<p>1 Q. Next page -- next paragraph</p> <p>2 says "Specificity." That's also a</p> <p>3 Bradford Hill aspect?</p> <p>4 A. I see where it says</p> <p>5 "specificity."</p> <p>6 Q. "Temporality" is also a</p> <p>7 Bradford Hill aspect?</p> <p>8 A. I see where it says --</p> <p>9 Q. Biologic gradient is also a</p> <p>10 Bradford Hill aspect?</p> <p>11 A. I see that.</p> <p>12 Q. Biologic plausibility?</p> <p>13 A. I see that section.</p> <p>14 Q. Coherence, they have that,</p> <p>15 correct?</p> <p>16 A. I see that section.</p> <p>17 Q. Okay. And all of those are</p> <p>18 the same -- that's the same framework</p> <p>19 that you used in your report, correct?</p> <p>20 You considered all those factors?</p> <p>21 A. I applied the Bradford Hill</p> <p>22 criteria when I looked at the totality of</p> <p>23 the data.</p> <p>24 Q. And those are the -- you</p>
Page 95	Page 97
<p>1 Hill criteria, correct?</p> <p>2 A. Mm-hmm.</p> <p>3 Q. And if you look on the next</p> <p>4 page?</p> <p>5 A. Wait. I'm sorry. I don't</p> <p>6 know if this is actually referring to the</p> <p>7 Bradford Hill criteria. It just says</p> <p>8 "Strength."</p> <p>9 Q. Well, if you look at the</p> <p>10 sentence above, it says Hill criteria,</p> <p>11 1965, the paragraph directly above?</p> <p>12 A. Okay.</p> <p>13 Q. Okay. So if you look at the</p> <p>14 next page, Page 20, it talks --</p> <p>15 MS. MILLER: You're positing</p> <p>16 that strength means strength of</p> <p>17 association? Is that --</p> <p>18 MR. TISI: Yes, correct.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Okay. Next -- next page it</p> <p>21 has consistency. That's also a Bradford</p> <p>22 Hill criteria?</p> <p>23 A. I see where it says</p> <p>24 consistency.</p>	<p>1 applied those same factors from Bradford</p> <p>2 Hill that I just described, you looked</p> <p>3 at -- you looked at -- you looked at</p> <p>4 strength, consistency, specificity,</p> <p>5 temporality, biologic gradient, biologic</p> <p>6 plausibility, and coherence. You looked</p> <p>7 at all of those things, correct?</p> <p>8 A. When I evaluate the totality</p> <p>9 of the data, I did look at all the</p> <p>10 criteria of the Bradford Hill --</p> <p>11 Q. Okay. Now --</p> <p>12 A. -- framework.</p> <p>13 Q. If you go to Page 19 of 21</p> <p>14 of the report?</p> <p>15 MS. MILLER: Of her report</p> <p>16 or of the draft analysis?</p> <p>17 MR. TISI: Of the draft --</p> <p>18 MS. MILLER: Draft screening</p> <p>19 assessment?</p> <p>20 MR. TISI: Of Exhibit Number</p> <p>21 4.</p> <p>22 BY MR. TISI:</p> <p>23 Q. On Page 28 at the very</p> <p>24 top --</p>

25 (Pages 94 to 97)

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<p>1 A. So we're not on 21?</p> <p>2 MS. MILLER: You said 19 to</p> <p>3 21.</p> <p>4 MR. TISI: I'm actually</p> <p>5 moving through. 28 at the very</p> <p>6 top.</p> <p>7 BY MR. TISI:</p> <p>8 Q. You would agree with me that</p> <p>9 after discussing the Bradford Hill</p> <p>10 criteria or Bradford Hill analysis that</p> <p>11 we just talked about before, they say the</p> <p>12 following: "The meta-analyses of the</p> <p>13 available human studies in the</p> <p>14 peer-reviewed literature indicate a</p> <p>15 consistent and statistically significant</p> <p>16 positive association between perineal</p> <p>17 exposure to talc and ovarian cancer.</p> <p>18 Further available data are indicative of</p> <p>19 a causal effect."</p> <p>20 Do you see that?</p> <p>21 MS. MILLER: Objection. You</p> <p>22 said after the Bradford Hill?</p> <p>23 I'm confused.</p> <p>24 THE WITNESS: It's on 28.</p>	<p>1 dishonest, let's go back. They say it</p> <p>2 again, exactly after -- on Page 21, after</p> <p>3 the discussion of coherence. They say</p> <p>4 the most -- do you see where it says,</p> <p>5 "The most recent meta-analyses detailed</p> <p>6 above (Taher, 2018) and consistent with</p> <p>7 the Hill criteria, suggest a small but</p> <p>8 consistent statistically significant</p> <p>9 positive association between ovarian</p> <p>10 cancer and perineal exposure to talc.</p> <p>11 Further available data are indicative of</p> <p>12 a causal effect."</p> <p>13 Do you see that?</p> <p>14 A. I see the words on that</p> <p>15 page. But I'd like to point out that --</p> <p>16 Q. No. There's no question</p> <p>17 pending.</p> <p>18 MS. MILLER: Excuse me. I</p> <p>19 think she should be allowed to</p> <p>20 finish her statement.</p> <p>21 MR. TISI: I'd like to point</p> <p>22 out. No. I asked her if those</p> <p>23 were the words -- did I read that</p> <p>24 correctly. There's nothing more</p>
Page 99	Page 101
<p>1 MR. TISI: You don't need to</p> <p>2 be.</p> <p>3 Yes.</p> <p>4 BY MR. TISI:</p> <p>5 Q. So after having looked at</p> <p>6 the Bradford Hill criteria, or Bradford</p> <p>7 Hill aspects, they say the following:</p> <p>8 "The meta-analyses of available human</p> <p>9 studies in the peer-reviewed literature</p> <p>10 indicate a consistent and statistically</p> <p>11 significant positive association between</p> <p>12 perineal exposure to talc and ovarian</p> <p>13 cancer. Further available data are</p> <p>14 indicative of a causal effect."</p> <p>15 Do you see that?</p> <p>16 MS. MILLER: Objection.</p> <p>17 That's a dishonest question.</p> <p>18 BY MR. TISI:</p> <p>19 Q. You can --</p> <p>20 A. That's what's written on the</p> <p>21 page there. They do say that.</p> <p>22 Q. Okay. And they say it</p> <p>23 again. Actually, if you go back. Since</p> <p>24 counsel was saying that I was being</p>	<p>1 to say, Counsel.</p> <p>2 MS. MILLER: I think we're</p> <p>3 ready for a break. I asked for a</p> <p>4 break five minutes ago.</p> <p>5 MR. TISI: I am just -- I'm</p> <p>6 just going to mark an exhibit, and</p> <p>7 then we'll move on.</p> <p>8 I'm going to attach the --</p> <p>9 MS. MILLER: Why don't we</p> <p>10 just mark it after the break?</p> <p>11 MR. TISI: No, I'm going to</p> <p>12 mark it right now.</p> <p>13 THE WITNESS: I would really</p> <p>14 like a break soon.</p> <p>15 MR. TISI: We're going to</p> <p>16 take it as soon as I mark it.</p> <p>17 I'm going to mark the Health</p> <p>18 Canada conclusion that I read into</p> <p>19 the record on Page 28, and I'm</p> <p>20 going to mark that as Exhibit 5.</p> <p>21 MS. MILLER: I'm going to</p> <p>22 object to that.</p> <p>23 THE WITNESS: The Health</p> <p>24 Canada draft conclusion.</p>

26 (Pages 98 to 101)

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<p>1 BY MR. TISI: 2 Q. Yes. 3 A. And I don't see draft there. 4 Q. Okay. We can -- it says -- 5 MS. MILLER: Also, where 6 does it say "conclusion" in the 7 document? 8 BY MR. TISI: 9 Q. -- it actually says -- it 10 says draft screening assessment. 11 MS. MILLER: Actually, 12 conclusion would be this 13 (indicating). The conclusion is 14 what's on Page 29. So I object -- 15 MR. TISI: That's not -- you 16 could -- you could say what you -- 17 MS. MILLER: I object to 18 this -- 19 MR. TISI: You can object. 20 Object. 21 MS. MILLER: Okay. Let me 22 finish. 23 MR. TISI: Object. Fine. 24 MS. MILLER: You are not</p>	<p>1 exhibit. Here you go. 2 (Document marked for 3 identification as Exhibit 4 Ballman-5.) 5 THE VIDEOGRAPHER: Off the 6 record? Remove your microphone 7 please. The time is 10:10 a.m. 8 (Short break.) 9 THE VIDEOGRAPHER: We are 10 back on the record. The time is 11 10:25 a.m. 12 BY MR. TISI: 13 Q. Doctor, going back to 14 Exhibit Number 5, the Health Canada 15 statement. We'll call it a statement. 16 The -- they use the word 17 consistent. 18 Do you see that? 19 A. So when I read this 20 statement -- and it's also referring to 21 meta-analyses. And so it appears that 22 it's not just one meta-analysis. So -- 23 so they are saying that the meta-analyses 24 are consistent.</p>
Page 103	Page 105
<p>1 letting me finish my sentence, 2 sir. 3 MR. TISI: I don't need -- 4 object is fine. 5 MS. MILLER: No, it's not 6 fine. 7 I object to this exhibit, 8 because the Health Canada 9 conclusion is actually on Page 29 10 where it says conclusion -- 11 MR. TISI: That's the 12 regulatory -- that's the 13 regulatory conclusion. 14 MS. MILLER: This is not a 15 conclusion. 16 MR. TISI: Okay. 17 MS. MILLER: So that's a 18 false statement there. Health 19 Canada conclusion. 20 MR. TISI: That's fine. You 21 can -- 22 MS. MILLER: Okay. I think 23 we're ready for a break? 24 MR. TISI: That's an</p>	<p>1 Q. Okay. And the meta-analyses 2 are made up of all of the -- of all of 3 the observational studies, correct? 4 A. But the meta-analyses are 5 all analyzing essentially the same data. 6 They are reworking the same data. So it 7 would be strange if they would come up 8 with quite different results. 9 Q. So -- and they are all 10 consistent, correct? 11 A. But as I said, they are -- 12 they are analyzing exact same data in 13 essentially the same way. And so it 14 would be very strange if they didn't come 15 up with similar numbers. 16 Q. But you -- you think there 17 is no consistency, correct, your opinion 18 is there is no consistency in the 19 observational studies, correct, or is 20 there consistency? 21 MS. MILLER: Objection. 22 THE WITNESS: When I applied 23 the Bradford Hill, I state that I 24 feel that the consistency criteria</p>

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<p style="text-align: right;">Page 106</p> <p>1 was not met. 2 BY MR. TISI: 3 Q. Okay. And they say that 4 there was consistency shown when they 5 looked at the meta-analyses, correct? 6 A. Well, they are saying 7 meta-analyses are consistent. But as I 8 said, they keep -- meta-analyses, these 9 meta-analyses are essentially all 10 analyzing the same data. So reworking 11 the same data is like doing a 12 replication. So one would expect that 13 the numbers are similar. 14 Q. Well, the meta-analyses, 15 depending upon their time frame, did not 16 all use the same studies, did they? 17 A. They -- the earlier ones 18 used a subset of the studies used in the 19 later ones, because there were additional 20 studies done since when the earlier ones 21 were done. 22 Q. So they -- so they were not 23 all the same, correct? 24 A. Essentially though, I mean</p>	<p style="text-align: right;">Page 108</p> <p>1 MS. MILLER: Objection. 2 THE WITNESS: So I'm not 3 sure what available data they are 4 referring to, and being indicative 5 of a causal effect, this is -- is 6 taken out of context. I would 7 have to go back and -- and read 8 through the entire document. I 9 mean, I don't know what basis. I 10 don't know what data that that's 11 like being based upon. 12 BY MR. TISI: 13 Q. Well, we went through that, 14 Doctor. We went through and that's why I 15 took the time and showed you all the 16 studies that they looked at. And I -- I 17 showed you the Bradford Hill aspects that 18 they analyzed and they went through all 19 of that. 20 And based upon what they 21 looked at, okay, they concluded that the 22 totality of the evidence was indicative 23 of a causal effect, correct? 24 MS. MILLER: Objection.</p>
<p style="text-align: right;">Page 107</p> <p>1 in -- in statistics and in epidemiology, 2 you know, reworking data that are not 3 completely independent of each other, we 4 would expect similar results and 5 correlation. 6 Q. And they say, "Further 7 available data are indicative of a causal 8 effect." 9 Do you see that? 10 A. I -- I see what's stated 11 there. I -- I have no idea what that is 12 based upon. That -- I do see that 13 statement. 14 Q. And you disagree with that, 15 correct? 16 A. I -- I don't know if I agree 17 or disagree with it. 18 Q. So -- 19 A. I mean I -- I -- that's what 20 they wrote. I do agree with that. 21 Q. Okay. Do you agree that the 22 available data is indicative of a causal 23 effect or you disagree with the 24 Canadian -- the Canadian assessment here?</p>	<p style="text-align: right;">Page 109</p> <p>1 THE WITNESS: I think you 2 just -- that's a slightly 3 different question. 4 BY MR. TISI: 5 Q. Okay. 6 A. But we didn't look at all 7 the studies that they looked at in terms 8 of, we just went through and -- and I 9 quickly glanced and saw that they had a 10 category that said strength, they had a 11 category that said -- I didn't look 12 through carefully to see what exact 13 studies they looked at. 14 Q. Did you -- didn't you do 15 that when you were preparing for your 16 deposition today, didn't -- weren't you 17 interested to see how they reached this 18 conclusion which was different than 19 yours? 20 A. I -- you know, I glanced and 21 I read through the document as you noted. 22 I did not cite it in my report. 23 Q. Mm-hmm. 24 A. I -- it's just a draft. So</p>

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<p style="text-align: right;">Page 110</p> <p>1 it could change. And I didn't want --</p> <p>2 all my report is essentially based upon</p> <p>3 published literature. I didn't want to</p> <p>4 incorporate a draft of something that</p> <p>5 might change, and we don't know which way</p> <p>6 they may change due to all the comments</p> <p>7 they get. The -- I believe it's out for</p> <p>8 comment right now, so...</p> <p>9 Q. Well, that was -- that's</p> <p>10 going to be my question too.</p> <p>11 First of all, Health Canada</p> <p>12 is not involved in this litigation to</p> <p>13 your knowledge, is it?</p> <p>14 A. I have no idea one way or</p> <p>15 the other.</p> <p>16 Q. But you are, you are a paid</p> <p>17 witness, correct?</p> <p>18 A. I'm --</p> <p>19 MS. MILLER: Objection.</p> <p>20 BY MR. TISI:</p> <p>21 Q. You're a paid -- you've been</p> <p>22 paid for your -- the work you did on your</p> <p>23 report, correct?</p> <p>24 A. I am an expert witness for</p>	<p style="text-align: right;">Page 112</p> <p>1 know what I mean.</p> <p>2 THE WITNESS: I billed for</p> <p>3 \$56,000.</p> <p>4 BY MR. TISI:</p> <p>5 Q. And -- and that will --</p> <p>6 A. And I anticipate I will be</p> <p>7 paid.</p> <p>8 Q. Right. And -- and you have</p> <p>9 incurred additional time from the time of</p> <p>10 your last billing until today, correct?</p> <p>11 A. Yes, I have.</p> <p>12 Q. Okay. About how much time?</p> <p>13 A. Probably on the order, 20,</p> <p>14 30 hours.</p> <p>15 Q. Okay. And so would it be</p> <p>16 fair to say that as of today, you will</p> <p>17 ultimately bill anywhere between 75 and</p> <p>18 \$100,000?</p> <p>19 A. If the math works out.</p> <p>20 Q. Okay. And so you are a paid</p> <p>21 expert in this case, true?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: I am being</p> <p>24 paid for my expert opinion.</p>
<p style="text-align: right;">Page 111</p> <p>1 Johnson &amp; Johnson. I really haven't been</p> <p>2 paid yet. I'm still waiting for --</p> <p>3 sorry.</p> <p>4 Q. Okay. You are going to --</p> <p>5 well, I am sure -- I am sure Susan is</p> <p>6 good for her -- good for her word on</p> <p>7 that. I'm sure she will pay you</p> <p>8 imminently.</p> <p>9 A. Yes.</p> <p>10 Q. But -- but you have been</p> <p>11 paid anywhere between, up and through, I</p> <p>12 saw your bill, up and through -- it's</p> <p>13 \$56,000. But I assume you've billed</p> <p>14 since then.</p> <p>15 How much have you --</p> <p>16 MS. MILLER: Objection. She</p> <p>17 just said she hasn't been paid,</p> <p>18 and you just said you have been</p> <p>19 paid.</p> <p>20 MR. TISI: Fine. I'm not --</p> <p>21 I'm not quibbling with you.</p> <p>22 MS. MILLER: Well, I mean,</p> <p>23 but just --</p> <p>24 MR. TISI: You know -- you</p>	<p style="text-align: right;">Page 113</p> <p>1 BY MR. TISI:</p> <p>2 Q. Okay. Now, would you agree</p> <p>3 with me -- let me put it this way. You</p> <p>4 would not write this -- you do not agree</p> <p>5 based upon your analysis of the evidence,</p> <p>6 with the statement in Exhibit Number 5</p> <p>7 from Health Canada. You would disagree</p> <p>8 with that, true?</p> <p>9 MS. MILLER: Objection.</p> <p>10 Asked and answered twice.</p> <p>11 MR. LOCKE: And I just want</p> <p>12 to assert an objection. I don't</p> <p>13 believe -- I believe there are</p> <p>14 words italicized here that are not</p> <p>15 italicized in the original.</p> <p>16 MR. TISI: And that's fine.</p> <p>17 You're exactly right, Tom.</p> <p>18 BY MR. TISI:</p> <p>19 Q. So I will make a</p> <p>20 representation I -- that I italicized</p> <p>21 those because I was going to ask you</p> <p>22 questions about those. But the record</p> <p>23 will reflect that those are not</p> <p>24 italicized in the original.</p>

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<p>1 That being the case, you 2 would not write the statement that Health 3 Canada did because you do not believe 4 that the data as a whole that you looked 5 at was indicative of a causal effect? 6 MS. MILLER: Objection. 7 THE WITNESS: Again, you 8 know, this is taken out of their 9 report at some section, and as we 10 discussed I believe it's not even 11 in their conclusions. And I -- I 12 don't know -- I mean, I wrote in 13 my expert report what I wrote. So 14 I don't have a statement in my 15 expert report that says this. 16 BY MR. TISI: 17 Q. And you would disagree with 18 that -- those statements, correct? 19 A. I just -- 20 MS. MILLER: Objection. 21 THE WITNESS: I just looked 22 at the data as a whole and did my 23 analyses and came up with the 24 conclusion that I came up with.</p>	<p>1 looked at are indicative of a causal 2 effect? 3 A. So it is my professional 4 opinion that there's no evidence of a 5 causal relationship between perineal or 6 genital talcum powder exposure and 7 ovarian cancer. 8 Q. So you do not think there's 9 a causal effect? 10 A. That is my opinion. 11 Q. Okay. So -- and Health 12 Canada, at least as of today, has a 13 contrary view, true, subject to your view 14 that they may change? But as of today, 15 they have a different view based upon 16 their analysis of the Bradford Hill 17 criteria, true? 18 MR. LOCKE: Objection. 19 MS. MILLER: Objection. 20 THE WITNESS: Yeah, I -- 21 I -- I would have to again read 22 through this carefully. 23 BY MR. TISI: 24 Q. Okay.</p>
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<p>1 Again, this is a draft. I 2 mean, I -- yeah. 3 BY MR. TISI: 4 Q. So your conclusion -- 5 A. I don't agree or disagree. 6 I'm just saying that -- 7 Q. So you don't disagree with 8 this? 9 A. I said I don't agree or 10 disagree. And I'm saying that when I 11 look at the science and I did my 12 analyses, I have put forward my 13 conclusion. 14 I obviously -- you know, 15 even if I believed what they did, I would 16 probably not have the exact same words. 17 That would be plagiarism. 18 Q. But you would just -- okay. 19 Let me ask you this statement. Let me 20 ask you the question directly. 21 Do you believe that the data 22 are indicative of a causal effect, 23 irrespective of this statement? Do you 24 believe that the data as a whole that you</p>	<p>1 A. I would agree that they did 2 not write a sentence exactly the way I 3 wrote a sentence there. 4 You know, again, I'd have to 5 read through this carefully to make sure 6 that this -- this -- this excerpt here 7 reflects the entirety of their analyses 8 and their opinions. 9 Q. Well, it's not unusual, 10 Doctor, for experts in epidemiology to 11 disagree on issues of causation when they 12 do their analysis, true? 13 A. It depends. 14 Q. Okay. Well, in many -- you 15 know, there are experts -- in fact, you 16 mention it in your report that some 17 experts believe that ovarian cancer -- 18 some people believe that ovarian cancer 19 can be caused by talcum powder; other 20 people don't. That's not unusual; is 21 that true? 22 A. So when I did my analyses 23 and looked at the data, I don't think 24 there's any scientific basis for any</p>

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<p>1 other opinion that there is no evidence, 2 credible evidence, of a causal 3 relationship between -- 4 Q. That is not my question. 5 You know, honestly, at some point I 6 really am going to have to call the 7 judge. 8 My question to you is, it is 9 not unusual for experts in epidemiology 10 to look at the same data and come to 11 different conclusions, true? 12 MS. MILLER: Please let her 13 finish her answer without -- 14 MR. TISI: Well, I'm not -- 15 I'm not going to sit -- 16 MS. MILLER: She was in the 17 middle of a sentence. 18 MR. TISI: I'm not -- I am 19 not going to sit here and listen 20 to her filibuster. I'm not going 21 to do it. 22 MS. MILLER: She's not 23 filibustering. She's answering 24 the question. You're trying to</p>	<p>1 and filibuster -- 2 MS. MILLER: She's not 3 filibustering. You're trying to 4 put words in her mouth. She is 5 trying to answer as an 6 epidemiologist from her scientific 7 experience, and you're trying to 8 put words in her mouth for sound 9 bytes you want. And you're 10 frustrated because she's trying to 11 give you honest, complete answers 12 as an epidemiologist. 13 MR. TISI: Oh, that's so 14 good of you. I'm so -- I'm so 15 glad that you said that. 16 BY MR. TISI: 17 Q. So, Doctor, in epidemiology, 18 cancer, cancer with cigarettes, for a 19 long time there was a debate in the 20 scientific community about whether 21 cigarettes cause cancer, true? 22 A. I haven't looked at that 23 literature in depth. I mean, possibly. 24 I mean, I'd have to --</p>
Page 119	Page 121
<p>1 put words in her mouth. 2 MR. TISI: I am not -- I'm 3 allowed -- 4 MS. MILLER: You're trying 5 to put words -- can you let me 6 finish my sentence? 7 MR. TISI: No, actually 8 yours -- 9 MS. MILLER: You're not 10 going to let me finish my 11 sentence? 12 MR. TISI: You're limited to 13 "objection." That's what you're 14 limited to in this deposition. 15 MS. MILLER: I think that if 16 you're not allowing -- 17 MS. SHARKO: I don't think 18 that's true. 19 MS. MILLER: -- the witness 20 to finish her sentences. I am 21 allowed to speak. And if you want 22 to call the judge, I am happy to. 23 MR. TISI: If your -- if 24 your witness is going to sit here</p>	<p>1 Q. Okay. It's not unusual in 2 the field of epidemiology for experts in 3 epidemiology to look at data and reach 4 different conclusions in their 5 professional judgment, true? 6 MS. MILLER: Objection. 7 THE WITNESS: So again, I -- 8 all I can say is I looked at the 9 data in its totality. I did the 10 analyses and wrote the report with 11 all sort of my methodology and how 12 I arrived at the opinions. And I 13 do not believe there's scientific 14 credible evidence that there is a 15 causal relationship between 16 talcum -- perineal talcum powder 17 exposure and ovarian cancer. To 18 me, that's the -- 19 BY MR. TISI: 20 Q. So, all right. 21 That wasn't my question. 22 And my question was a general question. 23 Having -- I'm going to take 24 talcum powder products out of -- out of</p>

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<p style="text-align: right;">Page 122</p> <p>1 the equation now. So you don't have to 2 answer me the question about what you did 3 in talc. Okay. 4 Is it not a true statement 5 that in general, epidemiologists when 6 looking at a causation question, can look 7 at the same data and reach different 8 conclusions? Does that not happen? 9 MS. MILLER: Objection. 10 THE WITNESS: I think it has 11 to depend upon what the question 12 is of interest and what level of 13 data are available. I mean, I 14 cannot answer that question 15 without knowing more specifics. 16 BY MR. TISI: 17 Q. Have you responded -- you 18 said there's a comment period. The 19 comment period was from December 6th 20 through February 6th. 21 Did you respond to 22 comment -- do you feel -- I gather you 23 feel strongly about your opinions, 24 correct?</p>	<p style="text-align: right;">Page 124</p> <p>1 again? 2 Q. Would you agree with me that 3 whether or not talcum powder products 4 cause ovarian cancer, the question you're 5 here to answer for us today, is an 6 important public health issue? 7 A. I believe what's an 8 important public health issue is -- is 9 trying to reduce the mortality from 10 ovarian cancer. 11 Q. Okay. And the question -- 12 you understand that there's been a debate 13 in the medical and scientific community 14 for decades on the question of whether or 15 not talcum powder products cause ovarian 16 cancer, correct? 17 MS. MILLER: Objection. 18 BY MR. TISI: 19 Q. IARC addressed it. FDA 20 addressed it. Health Canada addressed 21 it. It's been in the published 22 literature. You would agree with me on 23 that, right? 24 MS. MILLER: Are you asking</p>
<p style="text-align: right;">Page 123</p> <p>1 A. I don't know if I feel 2 strongly or not. I would say that I -- I 3 believe my opinions are based upon the 4 science. 5 Q. Well, you would agree with 6 me that ovarian cancer is a serious 7 disease? 8 A. It kills women. It's a 9 serious disease. 10 Q. Okay. And you would agree 11 with me that the mortality involved in 12 ovarian cancer is very, very high? 13 A. I -- I know that there are 14 different subtypes of ovarian cancer and 15 I -- the high grade serous has -- has -- 16 is not a very good prognosis. I agree a 17 lot of people die from it. 18 Q. And would you agree that 19 whether or not, irrespective of your view 20 of the evidence, whether or not talcum 21 powder products can cause ovarian cancer, 22 would be an important public health 23 issue? 24 A. What -- could you ask that</p>	<p style="text-align: right;">Page 125</p> <p>1 the last question that I objected 2 to or have you changed your 3 question? 4 BY MR. TISI: 5 Q. I'm asking you the question 6 I asked. You -- 7 MS. MILLER: Which? 8 BY MR. TISI: 9 Q. You understand that various 10 agencies have looked at this question, 11 that there has been a debate in the 12 medical and scientific community as to 13 the meaning of the science on ovarian 14 cancer and talc, true or not true? 15 MS. MILLER: Objection. 16 THE WITNESS: There is 17 different parts in there. What 18 I -- I would say is IARC looked at 19 the question. I'm not sure how 20 deeply the FDA has looked at it. 21 And I know that there's a draft 22 Health Canada document at this 23 point. So those agencies have 24 done something with respect to</p>

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<p>1 this.</p> <p>2 BY MR. TISI:</p> <p>3 Q. And you agree that the --</p> <p>4 the questions that they are wrestling</p> <p>5 with is an important one?</p> <p>6 MS. MILLER: Objection.</p> <p>7 THE WITNESS: Important in</p> <p>8 what sense?</p> <p>9 BY MR. TISI:</p> <p>10 Q. Important public health</p> <p>11 question. They are addressing an</p> <p>12 important public health question.</p> <p>13 A. If -- if there were evidence</p> <p>14 that there was a causal relationship</p> <p>15 between perineal and genital talcum</p> <p>16 exposure and ovarian cancer, if there was</p> <p>17 evidence that that is the case, then it</p> <p>18 would translate into a public -- probably</p> <p>19 a considerable public health.</p> <p>20 Q. Okay. And you feel strongly</p> <p>21 about your opinion that there is no such</p> <p>22 evidence, true?</p> <p>23 A. Again, my -- I don't -- I</p> <p>24 don't know how to use that word strongly.</p>	<p>1 Representatives held hearings on talc and</p> <p>2 causation. Do you know that?</p> <p>3 A. I did not know that.</p> <p>4 Q. Do you know that one of the</p> <p>5 epidemiologists, Dr. McTiernan, you know</p> <p>6 her?</p> <p>7 A. I know the name.</p> <p>8 Q. Okay. You know she appeared</p> <p>9 at that hearing. Do you know anything</p> <p>10 about that?</p> <p>11 A. Again, I -- I wasn't aware</p> <p>12 of the hearing so I do not know. I -- so</p> <p>13 I wouldn't know that she appeared.</p> <p>14 Q. Did J&amp;J ask you, say, you</p> <p>15 know, Dr. Ballman, you're an expert in</p> <p>16 the field of analyzing causation from an</p> <p>17 epidemiology standpoint, would you</p> <p>18 represent us before the House of</p> <p>19 Representatives on this important</p> <p>20 question?</p> <p>21 MS. MILLER: Objection.</p> <p>22 THE WITNESS: I was not</p> <p>23 contacted by J&amp;J to appear in a</p> <p>24 congressional.</p>
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<p>1 I believe that my evidence</p> <p>2 is -- my statement is based upon my</p> <p>3 scientific analyses of the data in</p> <p>4 total --</p> <p>5 Q. Have you shared --</p> <p>6 A. -- and is supported.</p> <p>7 Q. I apologize.</p> <p>8 Were you -- did you share</p> <p>9 that -- your opinions with Health Canada?</p> <p>10 A. I did not.</p> <p>11 Q. Okay. Did you -- have you</p> <p>12 tried to contact the FDA?</p> <p>13 A. I have not done that.</p> <p>14 Q. Have you contacted the</p> <p>15 National Cancer Institute to tell them</p> <p>16 there's no problem?</p> <p>17 MS. MILLER: Objection.</p> <p>18 THE WITNESS: I -- I</p> <p>19 wouldn't know who to contact. I</p> <p>20 don't even know if there's such a</p> <p>21 mechanism to do so.</p> <p>22 BY MR. TISI:</p> <p>23 Q. Okay. Well, you know last</p> <p>24 week the United States House of</p>	<p>1 BY MR. TISI:</p> <p>2 Q. Have you presented your</p> <p>3 opinions on the subject to your medical</p> <p>4 and scientific colleagues at Weill</p> <p>5 Cornell?</p> <p>6 MS. MILLER: Objection.</p> <p>7 THE WITNESS: I have not</p> <p>8 discussed this with my colleagues</p> <p>9 at Weill Cornell.</p> <p>10 BY MR. TISI:</p> <p>11 Q. I mean, there are -- you</p> <p>12 have an oncology division, and a</p> <p>13 gynecology division at Weill Cornell I</p> <p>14 assume?</p> <p>15 A. I'm not sure what their</p> <p>16 terms are. But there is a group that</p> <p>17 works on gynecology -- gynecology</p> <p>18 issues -- gynecology, and there is a</p> <p>19 hem/onc. And I don't know if they are</p> <p>20 divisions or departments, that sort of</p> <p>21 thing.</p> <p>22 Q. Have you reached out to them</p> <p>23 and said to -- to any of them, gee, you</p> <p>24 know, I have done this causation</p>

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<p>1 analysis, and, you know, you really could 2 tell women they can use talcum powder 3 products everyday for the next 40 years 4 and it be not be a problem in terms of 5 increasing their risk for ovarian cancer. 6 MS. MILLER: Objection. 7 BY MR. TISI: 8 Q. Have you done that? 9 MS. MILLER: Objection. 10 THE WITNESS: I -- I have 11 not contacted any -- I have not 12 discussed this with -- with any 13 one of my colleagues. 14 BY MR. TISI: 15 Q. If -- if one of your 16 colleagues at Weill Cornell, your 17 oncology colleagues, came up to you and 18 said look, I heard you were involved in 19 the -- looking at talcum powder products 20 and ovarian cancer for the -- in the 21 litigation involving Johnson &amp; Johnson, 22 you've done your analysis, do you think 23 it's okay if I tell my patients that they 24 can dust everyday for the next 30 years</p>	<p>1 that -- that that -- that that 2 issue has been raised, that -- 3 that -- I don't know who is saying 4 that there may be asbestos in 5 talcum powder. 6 BY MR. TISI: 7 Q. So you have not reviewed 8 evidence in this case that asbestos may 9 or may not be in the talcum powder 10 products that Johnson &amp; Johnson sold? 11 MS. MILLER: Objection. 12 THE WITNESS: So I believe 13 my opinion -- my -- not believe. 14 But my opinion is based upon 15 talcum powder, whatever it's 16 composed of. So I don't know 17 what's in it. But talcum powder, 18 whatever it's composed of, I don't 19 find any evidence -- or credible 20 evidence that there's a causal 21 relationship. 22 BY MR. TISI: 23 Q. Well, if there was asbestos 24 in talcum powder products, would you, if</p>
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<p>1 and it won't increase the risk? 2 MS. MILLER: Objection. 3 THE WITNESS: I -- I would 4 say it's my professional opinion 5 that there's no evidence of a 6 causal relationship between 7 perineum-talcum powder exposure 8 and ovarian cancer. 9 I'm not a gynecologist. So 10 I would not presume to tell a 11 gynecologist what they should tell 12 their patients with -- with 13 respect to anything. 14 BY MR. TISI: 15 Q. Now, you do understand that 16 in this case there is an allegation that, 17 among other things, that talcum powder 18 products used by -- manufactured and sold 19 by J&amp;J contained asbestos. Have you seen 20 that? 21 MS. MILLER: Objection. 22 THE WITNESS: I think I saw 23 somewhere in the media, it might 24 have been a tweet or something,</p>	<p>1 that same oncologist at Weill Cornell 2 came up to you and said Dr. -- 3 Dr. Ballman, I know that you are involved 4 in litigation. You've looked at the 5 causation question. If there is asbestos 6 in the talcum powder that my patients 7 use, is that okay for her to dust every 8 day? What would you tell them? 9 MS. MILLER: Objection. 10 THE WITNESS: I would say 11 the same thing I answered to the 12 talcum powder question, because I 13 analyze whether or not there's 14 evidence of a causal relationship 15 between talcum powder -- whatever 16 is in it -- I have no idea what's 17 in it -- causes ovarian cancer. 18 And so I would say that 19 that's my opinion. And again I 20 would not presume to tell a 21 gynecologist what they should tell 22 their patients one way or another, 23 because I am not an M.D. 24 BY MR. TISI:</p>

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<p>1 Q. Well, one of the -- one of 2 the aspects of Bradford Hill -- and we're 3 going to talk about this -- is the issue 4 of biologic plausibility, correct? 5 A. That is one of the criteria 6 within the Bradford Hill framework. 7 Q. If -- I'm going to ask you 8 to assume for the purposes of my question 9 that talcum powder products -- you would 10 agree with me that asbestos is a 11 carcinogen, correct? 12 MS. MILLER: Objection. 13 THE WITNESS: I have not 14 looked into the talcum powder data 15 and literature. So I only know 16 that there seems to be a strong 17 association that increases the 18 risk of mesothelioma, so a risk 19 factor for sure, between asbestos 20 exposure and mesothelioma. 21 BY MR. TISI: 22 Q. And looking at the issue of 23 whether or not there's a biologically 24 plausible explanation for the</p>	<p>1 me -- let me ask you this way. Let me 2 give you a hypothetical. Let me withdraw 3 the question. 4 Okay. If we had a bottle, 5 and the bottle was full of asbestos and 6 nothing else. Would you tell -- would 7 you tell a woman that she could use it to 8 dust her perineal -- her perineum? 9 MS. MILLER: Objection. I 10 think she said -- 11 MR. TISI: I don't -- I 12 don't care what you think she 13 said. Objection. 14 MS. MILLER: You've asked 15 this question 100 times. 16 MR. TISI: I'm asking -- I'm 17 asking -- 18 MS. MILLER: She said she 19 doesn't give advice. 20 MR. TISI: She's not. I'm 21 asking -- I'm asking you a 22 hypothetical. 23 BY MR. TISI: 24 Q. If -- if I had a bottle of</p>
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<p>1 increased -- an association, would the 2 presence of a carcinogen be important to 3 look at? 4 A. So looking at biological 5 plausibility, what would be important is 6 that in the biological experiments that 7 are done, that they use talcum powder, 8 the same type of talcum powder that women 9 use, to see if that talcum powder leads 10 to transformation in animals, let's say, 11 to ovarian cancer. 12 Q. But if one of the components 13 was a known carcinogen, wouldn't that be 14 a plausible explanation for the 15 association seen in the meta-analyses? 16 MS. MILLER: Objection. 17 THE WITNESS: Again, I mean, 18 the question isn't asbestos. The 19 question is whether talcum powder, 20 however it's composed -- 21 BY MR. TISI: 22 Q. And if it's composed 23 partially of asbestos, if it's composed 24 partially of asbestos -- let me -- let</p>	<p>1 pure asbestos, would that be a 2 biologically -- let me -- let me give you 3 a different hypothetical. 4 MS. MILLER: Are you 5 striking the question? 6 MR. TISI: Yes, I am, 7 Counsel. 8 BY MR. TISI: 9 Q. If I had five epidemiology 10 studies all showed an increased risk of 11 ovarian cancer and asbestos, and I had a 12 bottle of asbestos, would you say that 13 that would be okay to dust on the 14 perineum? 15 MS. MILLER: Objection. 16 THE WITNESS: So that's 17 difficult. First of all, I would 18 want to know what the five 19 epidemiology studies are, if there 20 are, you know, observational 21 studies. I mean, I don't know. 22 I would need to know the 23 dose. The dose makes the poison. 24 I don't know. I did not do any</p>

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<p style="text-align: right;">Page 138</p> <p>1 study on asbestos, so I wouldn't 2 render an opinion to a woman what 3 she should or should not use in 4 general either. 5 BY MR. TISI: 6 Q. Would you tell a family -- 7 would you tell a family member it's okay 8 to dust with asbestos? 9 MS. MILLER: Please stop 10 interrupting her answers, please. 11 BY MR. TISI: 12 Q. Would you tell a family 13 member that it's okay to dust with 14 asbestos? 15 A. Yeah, again, this is a 16 hypothetical. 17 Q. Absolutely. 18 A. I mean, you know, I -- I 19 wouldn't say -- I -- I wouldn't say one 20 way or the other. I would have to look 21 at the literature and see sort of whether 22 or not that that would be -- I don't know 23 asbestos. And so that's why I'm having a 24 hard time answering this question.</p>	<p style="text-align: right;">Page 140</p> <p>1 I can't imagine why anyone would dust 2 with asbestos. So my question -- my 3 second question would be, if the bottle 4 was half asbestos and half talc, would 5 you say that that would be okay? 6 MS. MILLER: Objection. 7 THE WITNESS: So my -- what 8 I was going to try to finish in 9 the last one is, it would be like 10 if it were something -- if it were 11 full of cinnamon and someone came 12 to me and said, can I dust with 13 cinnamon? I mean, why would you 14 want to dust with cinnamon. I -- 15 I mean, that's a weird question to 16 me. 17 BY MR. TISI: 18 Q. And so the question -- why 19 would you want to dust with asbestos, 20 right? 21 A. Well, I -- you know, I'm not 22 seeing a purpose for doing it. 23 Q. I'm asking you from a 24 safety -- from a safety perspective.</p>
<p style="text-align: right;">Page 139</p> <p>1 Q. Okay. So just the record is 2 clear, if I had a bottle of asbestos and 3 you were advising a family member and a 4 family member came to you and said, 5 "Dr. Ballman, do you think it's okay if I 6 dust with asbestos," you wouldn't know 7 what answer to give? You'd say I have to 8 take out the literature and look at it? 9 MS. MILLER: Objection. 10 Maybe -- you don't need to have 11 those facial expression. 12 THE WITNESS: I mean, that's 13 a real hypothetical, because I 14 couldn't imagine anyone coming to 15 me and saying can they dust with 16 asbestos. So that's why I'm 17 having a hard time answering this 18 question. I just don't see any -- 19 any -- what would be the purpose 20 of dusting with asbestos? What 21 would be the -- I just don't -- 22 BY MR. TISI: 23 Q. Honestly I can't imagine 24 either. So let me ask you the question.</p>	<p style="text-align: right;">Page 141</p> <p>1 Let's assume there was a purpose -- I'm 2 going to add to my hypothetical. 3 Let's assume there was a 4 purpose to do it, and somebody came up to 5 you and said, "I think it's -- I think 6 I'd like to dust with asbestos." 7 Would you say that that 8 would be okay? 9 MS. MILLER: Objection. 10 THE WITNESS: I just can't 11 imagine that situation. 12 BY MR. TISI: 13 Q. Okay. 14 A. So it's very -- I can't 15 answer that. 16 Q. I'm asking -- bear with me 17 in the hypothetical. We're allowed to do 18 that in a deposition. 19 If -- if -- if there were a 20 reason and somebody came up to you and 21 asked you for advice. Would you say to 22 them, sure, dust with asbestos? 23 MS. MILLER: Objection. 24 THE WITNESS: So, what I</p>

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<p style="text-align: right;">Page 142</p> <p>1 feel comfortable in saying, and 2 this is what I addressed, is if 3 that cup were full of talcum 4 powder and someone really would 5 have asked my opinion as to 6 whether or not they should use it, 7 I would just say it's my 8 professional opinion that, you 9 know, whatever is in there, you 10 know, that's no causal 11 relationship between dusting on 12 the perineum and ovarian cancer. 13 BY MR. TISI: 14 Q. Okay. And that would 15 include, whatever in there, if there is 16 asbestos in there? 17 A. Well, whatever talcum 18 powder, that's the literature I looked 19 at, whatever that talcum powder is 20 composed of, there is no evidence that 21 it -- credible evidence that it causes 22 ovarian cancer. 23 Q. Let me switch topics again. 24 Go to Exhibit Number 1,</p>	<p style="text-align: right;">Page 144</p> <p>1 A. Unless new information comes 2 to light. 3 Q. Okay. Does it fully 4 describe the methodology that you use to 5 reach your opinions? 6 A. I -- I don't know what you 7 mean by fully. But I do explain the 8 methodology that I used and -- and 9 provide bases for why I come to 10 conclusions. 11 Q. Did you grade the evidence 12 giving numerical values? Did you say, 13 well, this is a four on a scale of five, 14 this is a two on a scale of five, you 15 didn't do that, right? 16 A. Grade what evidence? 17 Q. Any of the evidence you 18 used. Did you provide -- in weighing the 19 evidence, did you grade them? 20 MS. MILLER: Objection. 21 BY MR. TISI: 22 Q. Did you provide any 23 numerical values? 24 A. I'm -- I'm confused by the</p>
<p style="text-align: right;">Page 143</p> <p>1 which is the report you were going to -- 2 you gave. 3 A. Yes, I'm there. 4 Q. Okay. Front page says -- 5 I'm sorry, let me -- let me just -- you 6 signed that page, correct? 7 A. Yes. 8 Q. Was every talc-specific 9 opinion contained in this report reached 10 after meeting with the J&amp;J lawyers? 11 MS. MILLER: Objection. 12 This has been addressed already 13 before. 14 BY MR. TISI: 15 Q. Yeah, okay. 16 A. This -- this entire report 17 and all the research done for this report 18 was done after I started working on 19 this -- well, I did it as part of 20 generating this report which happened 21 after November 2018. 22 Q. Does the report give all the 23 opinions you're prepared to give in this 24 case?</p>	<p style="text-align: right;">Page 145</p> <p>1 question. I mean, when one does 2 research, it's not common to grade every 3 piece of data that's on hand in any -- 4 any way. So I'm not sure. So I -- I 5 think I don't understand your question. 6 Q. Thank you. I appreciate 7 that. 8 Now, we discussed this 9 before, but you employed what are called 10 the Bradford Hill analysis, correct? 11 A. Something along those terms. 12 Q. Okay. 13 MR. TISI: And for the 14 record, I want to attach as 15 Exhibit Number 6 Dr. Hill's 16 article. 17 (Document marked for 18 identification as Exhibit 19 Ballman-6.) 20 BY MR. TISI: 21 Q. Is this the article, 1965 22 article that you were referring to in 23 your report? 24 A. Yes.</p>

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<p>1 Q. Thank you.</p> <p>2 Is this a -- is it fair to</p> <p>3 say that in the field of epidemiology, as</p> <p>4 you understand it, this is a seminal --</p> <p>5 seminal analysis of how to do a causation</p> <p>6 analysis?</p> <p>7 A. I would say it -- it</p> <p>8 provides the framework for how</p> <p>9 epidemiologists go about in determining</p> <p>10 whether there is a causal relationship.</p> <p>11 Q. And while there are a lot of</p> <p>12 published articles out there, you would</p> <p>13 consider this to be a fairly important</p> <p>14 piece of -- this would be, you know, kind</p> <p>15 of a different category in terms of its</p> <p>16 impact on how we look at causation</p> <p>17 questions?</p> <p>18 A. Again, I think I -- I would</p> <p>19 say it sort of frames today how -- how</p> <p>20 people evaluate causation questions.</p> <p>21 It's -- it's the first basis of it.</p> <p>22 Q. When is -- prior to meeting</p> <p>23 with the lawyers in this case, had you</p> <p>24 ever seen the Hill criteria -- had you</p>	<p>1 keep piling question -- objection.</p> <p>2 I'd like to say something.</p> <p>3 You keep piling question</p> <p>4 upon question upon question so --</p> <p>5 MR. TISI: Objection is --</p> <p>6 MS. MILLER: Okay.</p> <p>7 MR. TISI: Objection is</p> <p>8 fine, Counsel.</p> <p>9 MS. MILLER: And I think</p> <p>10 it -- it's impossible for her to</p> <p>11 know which question to answer. I</p> <p>12 don't think it's fair.</p> <p>13 MR. TISI: How about the</p> <p>14 last one?</p> <p>15 Well, when she looks at</p> <p>16 me --</p> <p>17 THE WITNESS: Can you repeat</p> <p>18 the last one, please?</p> <p>19 MR. TISI: Yes.</p> <p>20 MS. MILLER: Can you just</p> <p>21 try to ask one question at a time.</p> <p>22 That's all I ask.</p> <p>23 BY MR. TISI:</p> <p>24 Q. Is -- is there -- is there</p>
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<p>1 ever seen the Hill article?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And is the Hill</p> <p>4 criteria applied any differently</p> <p>5 depending upon where you live?</p> <p>6 In other words, do -- do</p> <p>7 people in France apply the Hill criteria</p> <p>8 the same way they apply it in the United</p> <p>9 States?</p> <p>10 MS. MILLER: Objection.</p> <p>11 BY MR. TISI:</p> <p>12 Q. People in England apply it</p> <p>13 the same way they apply it in Canada?</p> <p>14 MS. MILLER: Is that -- is</p> <p>15 that --</p> <p>16 BY MR. TISI:</p> <p>17 Q. I'm -- I'm asking you</p> <p>18 geographically. Is there -- if anyone</p> <p>19 were to stand up in court and say well,</p> <p>20 you know, this is an English scientist</p> <p>21 and, therefore, they apply it differently</p> <p>22 in England than they apply it in the</p> <p>23 United States.</p> <p>24 MS. MILLER: I think you</p>	<p>1 any --</p> <p>2 MS. MILLER: I'll object</p> <p>3 less that way.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Is there any difference</p> <p>6 between how scientists approach a</p> <p>7 causation question depending upon where</p> <p>8 they happen to live and practice?</p> <p>9 A. I believe that</p> <p>10 epidemiologists apply this criteria. I</p> <p>11 have no evidence that it would be</p> <p>12 dependent upon geographic location of --</p> <p>13 of the epidemiologist.</p> <p>14 Q. Okay. And so for example,</p> <p>15 we use the issue, we -- we looked at the</p> <p>16 Health Canada report before. You have no</p> <p>17 reason to believe that they apply the --</p> <p>18 the Bradford Hill criteria different in</p> <p>19 Canada than they do in the United States?</p> <p>20 A. I -- I think any good</p> <p>21 epidemiologist would -- would apply</p> <p>22 scientifically based methods to -- to</p> <p>23 come up with their conclusions.</p> <p>24 Q. Okay. And certainly the</p>

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<p>1 Hill framework is a scientifically based 2 framework for looking at causation? 3 A. It provides a framework in 4 which people can look at -- at the issue 5 of causation. 6 Q. Okay. Did you write your 7 general causation report Exhibit 1? 8 A. I wrote everything in it 9 except for -- title. Except for the 10 materials reviewed and considered piece. 11 Q. Okay. And are all the words 12 and sentences in the report yours? 13 A. I -- I wrote the entire 14 report. 15 Q. Did the lawyers for J&amp;J 16 write any of the words and sentences 17 contained in your report? 18 A. I -- I wrote the entire 19 report. 20 Q. When did you actually start 21 to write the report? 22 A. From the beginning, 23 essentially. Because as I was reviewing 24 the literature, I -- I put sections into</p>	<p>1 expert witness? Have you told anybody 2 that? 3 MS. MILLER: Objection. 4 THE WITNESS: Have I told 5 someone that it -- 6 BY MR. TISI: 7 Q. Have you ever told anybody, 8 you know, being an expert witness I can 9 make a little extra money, or words to 10 that effect? 11 MS. MILLER: Objection. 12 THE WITNESS: Not that I 13 recall. 14 BY MR. TISI: 15 Q. If you go to Page 21 of your 16 report -- actually, let me change it. 17 You rely on the -- you look 18 at the observational studies and 19 evidence, correct? 20 A. I -- I -- I looked at 21 observational studies as part of my 22 analyses. 23 Q. And in addition you looked 24 at the biologic evidence and that's on</p>
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<p>1 a document that was the basis of my 2 report. 3 Q. When did you first start 4 becoming an expert witness? I know you 5 were involved in the Viagra case and I -- 6 When did you -- when did you 7 first make yourself available as an 8 expert witness in litigation? 9 MS. MILLER: Objection. 10 THE WITNESS: I never made 11 myself available as an expert 12 witness. I was contacted first by 13 Sidley Austin with respect to a 14 patent case. But they contacted 15 me. I didn't even know how that 16 came about. 17 BY MR. TISI: 18 Q. Okay. And when would that 19 have been? 20 A. You are stretching my memory 21 now. 2016. 22 Q. Have you ever told anybody 23 that you think it would be a good way to 24 make additional money to be a -- to be an</p>	<p>1 Page 48 and 49 of your report? 2 A. 48 and 49? 3 Q. Mm-hmm. I'm sorry. I must 4 have mistyped it. I apologize. Maybe 5 it's 38 and 39. 6 MS. MILLER: There's a table 7 of contents. 8 BY MR. TISI: 9 Q. Yeah, that may have it. On 10 Page 36. 11 A. Yes, I'm there. 12 Q. And that contains your 13 analysis of the non-epidemiologic 14 evidence, correct? 15 A. I don't think I would call 16 it non-epidemiologic evidence. I mean, 17 biological plausibility is part of the 18 Bradford Hill criteria. And that's what 19 epidemiologists use to -- 20 Q. Okay. Now, going back to 21 your conclusion, you say there was no 22 evidence of a causal relationship between 23 perineal and genital talcum powder 24 exposure and ovarian cancer, correct?</p>

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<p>1 A. That's what I state. 2 Q. And that's -- those are your 3 words? 4 A. Those are my words. 5 Q. And isn't it true that 6 outside of litigation -- now, this is a 7 litigation report. This was paid for by 8 Johnson &amp; Johnson for the work that you 9 did, correct? 10 MS. MILLER: Objection. 11 There's two questions. 12 BY MR. TISI: 13 Q. The report -- the generation 14 of this report was paid for by Johnson &amp; 15 Johnson? 16 MS. MILLER: Objection. 17 THE WITNESS: I did this 18 report as part of my expert 19 witness activities on the behalf 20 of Johnson &amp; Johnson. 21 BY MR. TISI: 22 Q. For which you are paid? 23 A. For which I am paid. 24 Q. Okay. And isn't it true</p>	<p>1 BY MR. TISI: 2 Q. Well, I'm going to show you 3 one. Do you know who Dr. Narod is? 4 A. Not personally. 5 Q. Do you know him 6 professionally by reputation? 7 A. I know that I read an 8 article that he had published. 9 Q. Okay. And this article is 10 in Gynecologic Oncology. It's in your 11 report. 12 A. Yes. It's published in 13 Gynecologic Oncology. 14 Q. And it's an article entitled 15 "Talc and Ovarian Cancer"? 16 A. Yes. 17 Q. And it's an -- is this a 18 respected peer-reviewed journal? 19 A. I don't know what the impact 20 factor is of this journal. It is a 21 peer-reviewed journal. 22 Q. Does impact factor always 23 reflect the quality of the journal, the 24 actual academic quality of the journal?</p>
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<p>1 that experts outside of litigation have 2 published the opinion that you expressed 3 here as disingenuous? 4 A. Can you show me? 5 Q. I'm going to. Have you 6 ever -- have you ever seen a description 7 of -- of that opinion as being 8 disingenuous? 9 MS. MILLER: Objection. 10 BY MR. TISI: 11 Q. In the published literature? 12 A. Not to my knowledge. Can I 13 see -- 14 Q. Sure. 15 A. -- what you're referring 16 to -- what you're referring to? 17 Q. Do you know of a -- do you 18 know of a publication by a Steven Narod, 19 M.D.? 20 A. Which publication? I'm sure 21 he has many. 22 (Document marked for 23 identification as Exhibit 24 Ballman-7.)</p>	<p>1 A. It depends upon who you talk 2 to. So journals that have high impact 3 factors tend to think it does. Probably 4 more than journals with low impact 5 factor. But in general, I think the 6 higher the impact factor there is a 7 correlation with the quality of the 8 journal. 9 Q. Have you published in 10 relatively low impact journals? 11 A. I have. 12 Q. So you don't have a 13 criticism of anybody who publishes in 14 a -- in a low impact journal, do you? 15 A. I don't know. That's a 16 broad question. 17 Q. Well we had some testimony 18 the other day from a witness who said, 19 "Well, only if it's a high impact" -- 20 paraphrasing, and I am paraphrasing, that 21 low impact journals are not as 22 significant as high impact journals in 23 terms of their scholarly -- scholarly 24 importance.</p>

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<p style="text-align: right;">Page 158</p> <p>1 MS. MILLER: Objection.  2 THE WITNESS: That's just  3 really broad. I mean, I think my  4 take on it is that high impact  5 journals have definitely probably  6 more of a rigorous peer review  7 process than do some lower impact  8 journals. But that -- that is not  9 an absolute.  10 BY MR. TISI:  11 Q. Because you publish --  12 A. But I'm sure there's --  13 Q. Because you publish in --  14 A. -- exceptions.  15 Q. -- low impact journals,  16 right?  17 MS. MILLER: Objection.  18 Please stop interrupting  19 her.  20 BY MR. TISI:  21 Q. You publish in low impact  22 journals, correct?  23 A. I have. I don't -- I'm sure  24 there are some of the publications on my</p>	<p style="text-align: right;">Page 160</p> <p>1 exactly where you're reading?  2 Q. Sure. I'll show you mine.  3 A. Oh, there, thank you. Thank  4 you.  5 MS. SHARKO: Can I see it?  6 MR. TISI: You have it right  7 there.  8 MS. SHARKO: Thank you.  9 BY MR. TISI:  10 Q. It is unlikely that the  11 association between talc and ovarian  12 cancer is due to confounding, and so it  13 is fair to say that if there's a  14 statistically -- a statistically robust  15 relationship between talc and ovarian  16 cancer, it is likely to be causal, albeit  17 with intermediate factors, such as  18 inflammation. In any case, given the  19 number of hazard ratios in the literature  20 between 1.1 and 1.4 in both case-control  21 and cohort studies, it's disingenuous to  22 state there is no evidence that talc is  23 associated with ovarian cancer.  24 Do you see that?</p>
<p style="text-align: right;">Page 159</p> <p>1 list that are in lower impact journals  2 than others.  3 Q. Okay. Now, if I go to the  4 Narod article which is on your reference  5 list or on one of the lists. I forget  6 which one it is.  7 On the bottom of the  8 left-hand column, on the bottom, it  9 says -- I'm reading --  10 MS. MILLER: What page are  11 you on?  12 BY MR. TISI:  13 Q. From about --  14 MR. TISI: The second page.  15 BY MR. TISI:  16 Q. Left-hand column, about  17 60 percent of the way down.  18 Okay. It says the  19 following: And I'm going to read it, and  20 you tell me whether I read it correctly.  21 It is unlikely that the  22 association between talc and ovarian  23 cancer --  24 A. Wait, wait. Can I find</p>	<p style="text-align: right;">Page 161</p> <p>1 A. I do see that. You did read  2 that correctly.  3 Q. Okay. I'm going to have  4 that statement of Dr. Narod --  5 MS. MILLER: I was just  6 going to say you left one word out  7 in your reading --  8 MS. SHARKO: I think he  9 says --  10 THE WITNESS: Oh, you didn't  11 read that correct.  12 MR. TISI: I thought you  13 said you did read -- did I --  14 THE WITNESS: I'm sorry.  15 BY MR. TISI:  16 Q. I'll read it again. Let me  17 put it in front of you.  18 (Document marked for  19 identification as Exhibit  20 Ballman-8.)  21 BY MR. TISI:  22 Q. This is Exhibit Number 8.  23 And I've highlighted --  24 MS. MILLER: Again, this is</p>

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<p>1 called a conclusion but it comes 2 in the middle of the document. I 3 have -- 4 MR. LOCKE: This is 5 definitely -- I'm going to object. 6 This is definitely not the 7 conclusion. Read the last 8 paragraph. 9 MS. MILLER: I have an 10 objection to the mislabeling of so 11 far each of these exhibits. 12 MR. TISI: Let me tell you 13 what. I'm going to take out -- 14 you can block out the conclusion 15 if you want, if that will make you 16 happy, Counsel. 17 MS. MILLER: Thank you for 18 that offer. 19 MR. TISI: Okay. So you 20 won't do it. 21 BY MR. TISI: 22 Q. So, I'm -- Doctor, did I 23 read the statement correctly, that it is 24 unlikely that the association between</p>	<p>1 the -- the statement will be -- the 2 record will be -- 3 A. Yeah. 4 Q. -- from the article. 5 Do you see where it says, 6 "It's disingenuous to state that there is 7 no evidence that talc is associated with 8 ovarian cancer"? 9 A. Talc is -- 10 MR. TISI: Counsel, please. 11 MS. MILLER: I -- 12 THE WITNESS: "It is 13 disingenuous to state that there 14 is no evidence that talc is 15 associated with ovarian cancer." 16 BY MR. TISI: 17 Q. That's what he writes in his 18 non-litigation report, do you see it? 19 A. I -- I do see that. 20 Q. Okay. And you would 21 disagree with that statement, correct? 22 A. Well, I mean, it depends 23 upon how you parse things out. So you 24 know, it's disingenuous to state that</p>
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<p>1 talc and ovarian cancer is due to 2 confounding, and so it is fair to say 3 that if there's a statistically robust 4 relationship between talc and ovarian 5 cancer is likely to be causal, albeit 6 with intermediate factors such as 7 inflammation. 8 Did I read that correctly? 9 MS. SHARKO: No, you didn't. 10 Is the word use missing here 11 too? He misread that. 12 MS. MILLER: That word "use" 13 is missing again. 14 MR. TISI: "Talc use and 15 ovarian cancer is likely to be 16 causal." 17 Did I not say that? 18 MS. MILLER: "Talc use". 19 BY MR. TISI: 20 Q. Do you see that statement? 21 A. Yeah, I see that statement. 22 And I'll take your word you read it 23 correctly. 24 Q. The statement will be what</p>	<p>1 there is no evidence that talc is 2 associated with ovarian cancer. So if 3 you mean that there are no studies that 4 have a statistically significant 5 association, that would be correct. 6 Q. Okay. 7 A. He is not stating there that 8 there is no evidence that talc is -- that 9 talc is -- that there's a causal 10 relationship between talc and ovarian 11 cancer. 12 Q. What -- he also says that 13 there -- that the association between 14 talc and ovarian cancer is unlikely due 15 to confounding, do you see that in the 16 first sentence? 17 A. Yes. 18 Q. And you disagree with that, 19 true? 20 A. Now, which sentence, can you 21 read -- 22 Q. The first sentence. "It is 23 unlikely that the association between 24 talc and ovarian cancer" --</p>

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<p>1 A. Oh, that one. 2 Q. -- "is due to confounding." 3 Do you disagree with that? 4 MR. LOCKE: Objection to the 5 term, "the first sentence." 6 THE WITNESS: Yeah. 7 MR. TISI: The first -- 8 okay. 9 THE WITNESS: It's of that 10 document. 11 BY MR. TISI: 12 Q. Correct. Of -- of exhibit 13 that -- 14 A. This one. 15 Q. Correct. 16 A. 8? 17 Q. Yes. 18 A. I -- I don't see any 19 references there's -- references to 20 support that statement. 21 Q. So you would disagree with 22 the statement? 23 A. Well, I -- I don't see any 24 references to support that.</p>	<p>1 his conclusion wrong? 2 A. I -- I would have to see the 3 references upon which he's making that 4 conclusion in order to assess that. 5 The data I looked at in 6 totality, I do see evidence of 7 confounding. In fact, we can go to the 8 Schildkraut study, and -- and there is a 9 pretty resounding evidence there that 10 there is recall bias, which is -- 11 Q. After 2014, correct? 12 A. Well, there's recall bias -- 13 no, there's recall bias even before that. 14 But it shows sort of how 15 much magnitude recall bias can have just 16 due to tweaking one little thing. 17 But I did not say that 18 there's no recall bias before 2014. 19 Q. So would you defer to the 20 authors of that study as to what the 21 meaning of that data meant? 22 A. No. Scientists don't do 23 that. Scientists look at publications. 24 They look at -- they looked at the</p>
Page 167	Page 169
<p>1 Q. So you disagree with the 2 statement? 3 MS. MILLER: Objection. 4 THE WITNESS: I'm just 5 saying I don't see any 6 references -- 7 BY MR. TISI: 8 Q. I understand. I'm not 9 asking you whether you see references. 10 I'm asking you whether you disagree with 11 the statement. 12 A. I believe in any sort of 13 observational study it is not possible to 14 conclude that there is no confounding. 15 Q. Okay. That's not what he 16 said, did he? 17 He said, "It is unlikely 18 that the association between talc and 19 ovarian cancer is due to confounding." 20 Do you see that? 21 A. I see he says unlikely. But 22 again, I -- there's -- there's no 23 references to support that. 24 Q. Okay. So my question is, is</p>	<p>1 methods. The methods of to be published. 2 They look at the analyses that were done 3 and the results that were done. And -- 4 and they evaluate whether or not they -- 5 they believe to the strength that the 6 authors do, that the authors' conclusions 7 are supported by all that. 8 Q. Now, Dr. Narod published his 9 opinions, correct? 10 A. Are these opinions? Yeah? 11 Q. Okay. I'm going to -- I'll 12 characterize them as opinion. Okay. 13 He published these 14 statements, correct? 15 A. Yes. This is statements 16 made in a paper that was published. 17 Q. Okay. And so he submitted 18 his -- his views to the scientific and 19 medical community, correct? 20 A. Yeah. I mean, the -- all 21 the views that's in this entire article, 22 I mean, so, you know, there's more words 23 than this than just the -- the two 24 sentences that were pulled out.</p>

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<p>1 Q. I agree, I agree. But he 2 submitted his -- his views to the 3 scientific and medical community for what 4 that's worth, correct? 5 A. This paper has been 6 published. 7 Q. Okay. The Health Canada 8 paper, even in its draft form, was put on 9 the internet. That's where you found it, 10 correct? 11 A. The Health Canada draft is 12 available for people to review. 13 Q. Okay. And comment on, which 14 you have not done, right? 15 A. I have not commented on the 16 Health Canada. 17 Q. Have you published your 18 opinions about talc? 19 A. I did research on this. And 20 I wrote an expert report. I have not 21 published my expert report. 22 Q. Have you submitted your 23 report to peer review? 24 A. That's sort of -- that would</p>	<p>1 Canada did, just like any of the other 2 authors of the studies that you've 3 reviewed, what your views on the level of 4 evidence there is for the general 5 causation question. 6 Are you -- do you intend to 7 publish? 8 MS. MILLER: Objection. 9 Again, that was two questions. 10 The first one was the 11 objectionable one. 12 THE WITNESS: So -- 13 MR. TISI: Let me rephrase 14 the question. 15 BY MR. TISI: 16 Q. Do you intend to publish on 17 the question about whether or not ovarian 18 cancer is caused by talcum powder 19 products? 20 A. I do not plan to publish. 21 Q. Now, in addition to offering 22 your own professional opinion on the 23 sufficiency of the evidence on talc and 24 ovarian cancer, I understand you may</p>
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<p>1 be sort of odd. This -- this expert 2 report is written for a specific purpose. 3 If I'm going to do a peer-reviewed 4 article, it -- it would look a little 5 different from -- from this expert 6 report. 7 Q. So what specific purpose was 8 this article -- was this report written 9 for? 10 MS. MILLER: Objection. 11 THE WITNESS: So this report 12 was written to look at the 13 totality of the evidence that's 14 been published to determine 15 whether there is an association 16 between talc and ovarian cancer, a 17 causal relationship between talc 18 and ovarian cancer. 19 BY MR. TISI: 20 Q. Now, did you -- so would 21 you -- have you decided -- now that 22 you've done this review, are you going to 23 write a paper that would put out, just 24 like Dr. Narod did, just like Health</p>	<p>1 offer criticisms of plaintiffs' 2 epidemiology experts in this case; is 3 that true? 4 A. So, in my report, I point 5 out some -- I point out things that -- 6 other experts had said that -- that I 7 believe have limitations or that I don't 8 agree with. 9 Q. Well, for the record the 10 experts that you referred to in your 11 report are Jack Siemiatycki? 12 A. He's one expert. 13 Q. Do you know who Jack 14 Siemiatycki is? 15 A. I know who -- I know who he 16 is. But I've not met him. 17 Q. You understand that he's 18 well published in the field of cancer 19 epidemiology? 20 MS. MILLER: Objection. 21 THE WITNESS: I did not look 22 at his publication records. So I 23 don't know if he's well published 24 or not.</p>

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<p style="text-align: right;">Page 174</p> <p>1 BY MR. TISI: 2 Q. You know that he was the 3 chair of the IARC panel that dealt with 4 the issue of ovarian cancer and talc? 5 A. I believe when I read the 6 IARC -- I believe when I read his expert 7 report, that is what he stated. 8 Q. Do you have any reason to 9 believe that he's unqualified to offer 10 his opinions in this case on the general 11 question? Whether you disagree with his 12 conclusions, put that aside for a moment. 13 I'm asking you do you have 14 any qualms with his qualifications to 15 offer an opinion on the issue of general 16 causation? 17 MS. MILLER: Objection. 18 THE WITNESS: I don't think 19 it's my place to decide whether or 20 not someone has the qualifications 21 to offer an opinion. 22 BY MR. TISI: 23 Q. Well, we had a witness the 24 other day who said that he thought</p>	<p style="text-align: right;">Page 176</p> <p>1 epidemiologist and has -- I can't 2 remember if she's published in the area. 3 I presume she has. And, you know, one 4 can look at her publications. 5 Q. So I guess what I'm 6 hearing -- so let -- 7 THE VIDEOGRAPHER: Sorry. 8 You're covering your microphone. 9 BY MR. TISI: 10 Q. Let me summarize it. Do 11 you -- of any of plaintiffs' experts in 12 this case, do you intend to offer any 13 opinions that any of them are unqualified 14 to render an opinion on the general 15 causation question? 16 MS. MILLER: Objection. 17 THE WITNESS: I -- it's -- I 18 don't -- I was not asked to render 19 an opinion if I think that any of 20 the experts are unqualified or 21 not. And so I haven't seen 22 thought about that. 23 BY MR. TISI: 24 Q. And that's fine. Are all of</p>
<p style="text-align: right;">Page 175</p> <p>1 another one of plaintiffs' witnesses was 2 unqualified. I'm asking you, are you -- 3 do you think that this witness -- that 4 Dr. Siemiatycki is unqualified? 5 A. I believe he has -- he has 6 credentials in this area, and he's 7 done -- he was, as you said, the chair of 8 the IARC committee, and may even have 9 published in this area. 10 So, you know, when people 11 publish, yeah -- I don't know what the 12 word "qualified" means, but I think, you 13 know, he is a scientist. 14 Q. What about Anne McTiernan? 15 Do you have any qualms about her 16 qualifications to render an opinion on 17 the question of whether or not talc 18 causes ovarian cancer? 19 MS. MILLER: Objection. 20 THE WITNESS: I can't speak 21 to the qualifications. 22 BY MR. TISI: 23 Q. Okay. 24 A. I know that she's an</p>	<p style="text-align: right;">Page 177</p> <p>1 your opinions of these experts contained 2 in your expert report, Exhibit 1? 3 MS. MILLER: Objection. She 4 just said she has no opinions. 5 THE WITNESS: Are my 6 opinions of the actual experts? 7 BY MR. TISI: 8 Q. Yes. Of the actual experts, 9 of their conclusions, of their 10 methodology, are all of those opinions 11 contained in your expert report, Exhibit 12 Number 1? 13 MS. MILLER: Objection. I 14 don't understand that question. 15 MR. TISI: You don't have 16 to. As long as she understand it. 17 THE WITNESS: Yeah, I'm 18 confused too. 19 MS. MILLER: What? 20 THE WITNESS: Because I 21 thought I heard my opinions of the 22 experts -- 23 BY MR. TISI: 24 Q. I said --</p>

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<p>1 A. -- and I don't know why I 2 would have -- 3 Q. Are your criticisms of 4 your -- are all of the criticisms that 5 you have on plaintiffs' experts contained 6 in your expert report? 7 MS. MILLER: Her criticisms 8 of the experts' opinions? 9 MR. TISI: Yes. 10 MS. MILLER: Okay. That's 11 not what you said. 12 THE WITNESS: No, no, you 13 said experts. And so I'm still 14 confused. 15 BY MR. TISI: 16 Q. Okay. Are all of the 17 opinions related to plaintiffs' experts 18 contained in your expert report? 19 A. Are all my opinions related 20 to plaintiffs' experts? 21 Q. Mm-hmm. 22 A. Themselves? 23 Q. Mm-hmm. Of their opinions, 24 their methodology, any aspect --</p>	<p>1 number here. I disagree with that number 2 there, or I disagree -- so I guess I have 3 to say it's not complete. 4 Q. Okay. Are there any 5 opinions that you have as you sit here 6 today about any of the opinions that they 7 gave that are not in your report? 8 A. Without going through their 9 reports and going through my report to 10 make sure that every single criticism I 11 might have has been made, I can't answer 12 that with any sort of certainty. 13 Q. Okay. I'm going to have it 14 marked as Exhibit Number 9, your 15 curriculum vitae. 16 (Document marked for 17 identification as Exhibit 18 Ballman-9.) 19 BY MR. TISI: 20 Q. This is the one that was 21 provided with your expert report. Is 22 this your most recent curriculum vitae? 23 A. No. 24 Q. Is there one subsequent to</p>
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<p>1 A. Okay. That's a little 2 different. Again, I heard, are my 3 opinions of the qualifications, or 4 whatever -- of the experts. 5 Q. I said -- I'm reading 6 verbatim. Are all of the opinions 7 related to plaintiffs' experts that you 8 have contained in your expert report? 9 A. See, that says are my 10 opinions of all the plaintiff experts. 11 To me, that's like my opinions on the 12 experts themselves, which I did not 13 address. 14 Q. Okay. I said related to the 15 expert. Okay. Let me -- let me rephrase 16 the question. 17 Are all of your criticisms 18 about the opinions that plaintiffs' 19 experts will offer in this case contained 20 in your report? 21 A. I mean, the ones I thought 22 were -- the most important are in here. 23 I can -- you know, I didn't go through 24 and say, okay, I disagree with this</p>	<p>1 that? 2 A. This says June 5th on it. 3 Q. Okay. Is the expert 4 report -- 5 MS. MILLER: She's looking. 6 THE WITNESS: The thing 7 that's attached as Exhibit A on my 8 expert report says February 22nd. 9 BY MR. TISI: 10 Q. Okay. So let's -- 11 A. So -- 12 Q. That's an old one. I have 13 it says February 22nd there. Am I wrong? 14 MS. MILLER: The one that 15 you gave us says June 5th. 16 MR. TISI: Okay. My office 17 must have printed it out wrong. 18 BY MR. TISI: 19 Q. Okay. So is Exhibit A to 20 your expert report your most recent 21 curriculum vitae? 22 A. It's the most -- 23 MS. MILLER: Shall we just 24 all refer back to Exhibit 1 for</p>

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<p>1 this portion of the questioning?</p> <p>2 MR. TISI: Yes, correct.</p> <p>3 Exhibit A.</p> <p>4 MS. MILLER: Of your</p> <p>5 Exhibit 1?</p> <p>6 MR. TISI: Exhibit 1.</p> <p>7 MS. MILLER: Exhibit A to</p> <p>8 Exhibit 1.</p> <p>9 MR. TISI: Correct.</p> <p>10 MS. MILLER: Just so we're</p> <p>11 all on the same page.</p> <p>12 MR. TISI: Thank you.</p> <p>13 THE WITNESS: It's the</p> <p>14 latest one that I updated.</p> <p>15 BY MR. TISI:</p> <p>16 Q. Okay. Does this CV</p> <p>17 accurately summarize the experience that</p> <p>18 you believe qualifies you to render an</p> <p>19 epidemiologic opinion on the causation</p> <p>20 question in this case?</p> <p>21 A. That -- that's a broad</p> <p>22 question. I mean, I don't know if you</p> <p>23 can capture 20 years of -- of experience,</p> <p>24 you know, in one document, but it</p>	<p>1 correct?</p> <p>2 A. Not off the top of my head.</p> <p>3 Q. Okay. One more plaintiffs'</p> <p>4 epidemiology referred to in your expert</p> <p>5 report is April Zambelli-Wiener-Weiner.</p> <p>6 Do you remember? She looked at the</p> <p>7 Huncharek and Muscat publications in 2003</p> <p>8 and 2000 -- 2007, and then the 2011</p> <p>9 publication of the -- of their report to</p> <p>10 the FDA. Do you remember reading that?</p> <p>11 A. I remember reading her</p> <p>12 expert report. Can I -- can I see it? I</p> <p>13 don't remember if those were the actual</p> <p>14 studies that she -- I thought 2003 was --</p> <p>15 and I don't remember a 2011. So --</p> <p>16 Q. Okay. Let --</p> <p>17 A. -- but I did read her expert</p> <p>18 report.</p> <p>19 Q. Let's put aside 2011 for a</p> <p>20 moment. The diaphragm study, which was</p> <p>21 2007 and 2003 meta-analysis, you did read</p> <p>22 her report on those, correct?</p> <p>23 A. I read her expert report.</p> <p>24 Q. Okay. And you agree that</p>
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<p>1 captures, you know, some highlights, yes.</p> <p>2 Q. Well, is there anything that</p> <p>3 you can think of in your experience,</p> <p>4 beyond what is in your expert report as</p> <p>5 you sit here right now, that would</p> <p>6 qualify you to testify on the issue of</p> <p>7 whether or not ovarian cancer is caused</p> <p>8 by talcum powder products?</p> <p>9 A. Well, in the -- in the</p> <p>10 addition to what is written here is my</p> <p>11 day in and day out daily activities</p> <p>12 when -- that I do as part of my job.</p> <p>13 That -- that has built up the experience</p> <p>14 over the years.</p> <p>15 Q. When is the last time -- do</p> <p>16 any of your publications anywhere refer</p> <p>17 to the Bradford Hill criteria?</p> <p>18 A. I have no idea. Nothing</p> <p>19 comes to the top of my head, but I can't</p> <p>20 say with certainty.</p> <p>21 Q. Okay.</p> <p>22 A. As you mentioned, there's</p> <p>23 like 200 some.</p> <p>24 Q. But none you can think of,</p>	<p>1 those reports contain -- those studies</p> <p>2 contain errors, correct?</p> <p>3 A. Yeah. Can I see her expert</p> <p>4 report, please?</p> <p>5 Q. I don't have it with me.</p> <p>6 Do you -- do you have any</p> <p>7 opinions as to whether -- did you look --</p> <p>8 when you were preparing your report, did</p> <p>9 you look at her report and try to confirm</p> <p>10 or not the errors that she identified</p> <p>11 with respect to those studies?</p> <p>12 MS. MILLER: Objection.</p> <p>13 BY MR. TISI:</p> <p>14 Q. Was that part of what you</p> <p>15 were asked to do?</p> <p>16 MS. MILLER: Objection. I</p> <p>17 am sorry, objection after the</p> <p>18 first question. I didn't realize</p> <p>19 there would be two.</p> <p>20 THE WITNESS: So --</p> <p>21 BY MR. TISI:</p> <p>22 Q. Was it part of your -- in --</p> <p>23 in connection with preparing your expert</p> <p>24 report, did you look at whether or not</p>

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<p>1 there were substantive flaws in the</p> <p>2 analyses conducted by Drs. Huncharek and</p> <p>3 Muscat that Dr. Zambelli-Wiener-Weiner</p> <p>4 had identified?</p> <p>5 A. So you're asking me to</p> <p>6 remember, just off the top of my head</p> <p>7 what's in her report. I would very much</p> <p>8 like to see that report --</p> <p>9 Q. I'm asking you what you --</p> <p>10 I'm asking you what you did. Okay.</p> <p>11 Did you --</p> <p>12 A. I did look at her report and</p> <p>13 I did read through it.</p> <p>14 Q. Did you do any analysis of</p> <p>15 the Huncharek and Muscat articles?</p> <p>16 A. Oh, did I -- that's a</p> <p>17 different question. Did I do any</p> <p>18 analyses of their articles? I read</p> <p>19 through her report. I do remember that.</p> <p>20 I do remember her finding some error --</p> <p>21 or what she called errors, numbers that</p> <p>22 she couldn't match that they had reported</p> <p>23 in their report that came from other</p> <p>24 case-control studies and so forth.</p>	<p>1 of deposition --</p> <p>2 MS. MILLER: If you want</p> <p>3 Dr. Zambelli-Wiener-Weiner's</p> <p>4 report, we can have it brought in</p> <p>5 here.</p> <p>6 MR. TISI: I don't need to.</p> <p>7 BY MR. TISI:</p> <p>8 Q. This is the notice of</p> <p>9 deposition that we filed in this case.</p> <p>10 Have you seen that before?</p> <p>11 A. I have seen this document.</p> <p>12 Q. Okay. And you -- your</p> <p>13 counsel provided documents last night.</p> <p>14 And I'm not going to mark all of them.</p> <p>15 But because they will go out of order</p> <p>16 here, I'm going to mark them as 10, A, B,</p> <p>17 C, D, because they are in response to</p> <p>18 this notice of deposition.</p> <p>19 A supplemental list of</p> <p>20 materials, I'm going to have this marked</p> <p>21 as Exhibit Number 10A.</p> <p>22 (Document marked for</p> <p>23 identification as Exhibit</p> <p>24 Ballman-10.)</p>
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<p>1 And I -- I remember her</p> <p>2 doing various different analyses that if</p> <p>3 they really used the studies that they</p> <p>4 claimed they used, what would the</p> <p>5 dose-response relationship, say, look</p> <p>6 like. And I remember it didn't matter,</p> <p>7 because there still was no dose-response</p> <p>8 relationship even when she did the</p> <p>9 analyses in the way she thought it should</p> <p>10 have been done.</p> <p>11 Q. So other than that, do you</p> <p>12 have any criticisms of her?</p> <p>13 A. I would have to go through</p> <p>14 my -- my report here and -- and see if</p> <p>15 I -- I actually sort of mention anything</p> <p>16 with respect to her actual report. I</p> <p>17 don't remember off of the top of my head.</p> <p>18 Q. Now, Exhibit Number 10 is</p> <p>19 the -- I'm going to ask --</p> <p>20 (Document marked for</p> <p>21 identification as Exhibit</p> <p>22 Ballman-10.)</p> <p>23 BY MR. TISI:</p> <p>24 Q. I'm going to mark the notice</p>	<p>1 (Document marked for</p> <p>2 identification as Exhibit</p> <p>3 Ballman-10-A.)</p> <p>4 BY MR. TISI:</p> <p>5 Q. And this one, Number 2, is</p> <p>6 the Health Canada document that we marked</p> <p>7 previously.</p> <p>8 A. It has it on it here, yes.</p> <p>9 Q. Okay.</p> <p>10 (Document marked for</p> <p>11 identification as Exhibit</p> <p>12 Ballman-10-B.)</p> <p>13 (Document marked for</p> <p>14 identification as Exhibit</p> <p>15 Ballman-10-C.)</p> <p>16 (Document marked for</p> <p>17 identification as Exhibit</p> <p>18 Ballman-10-D.)</p> <p>19 BY MR. TISI:</p> <p>20 Q. The next is an addendum to</p> <p>21 list of materials reviewed and considered</p> <p>22 by Karla Ballman. And I'm going to have</p> <p>23 this marked as Exhibit Number 10-B.</p> <p>24 10-C is your invoice dated</p>

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<p style="text-align: right;">Page 190</p> <p>1 3/7/2019, the one that Ms. Sharko has not 2 paid. 3 MS. MILLER: It's Skadden. 4 I think it's me who hasn't paid. 5 MR. TISI: Okay. 6 MS. MILLER: I'm the bad guy 7 here. 8 BY MR. TISI: 9 Q. Next one is an e-mail I'm 10 going to ask you in a moment about, from 11 Dr. Karla Ballman to Sandra Oquendo at 12 the FDA. 13 Can you tell me what that's 14 about? 15 MS. MILLER: Is that a 16 question now? 17 MR. TISI: Yes. 18 MS. MILLER: Are you done 19 marking them? 20 MR. TISI: No, I'm not done 21 marking them. I'm just going to 22 stop right there. 23 MS. MILLER: Oh, okay. 24 BY MR. TISI:</p>	<p style="text-align: right;">Page 192</p> <p>1 exchange back and forth was to clarify 2 that you were? 3 MS. MILLER: Objection. 4 THE WITNESS: So can I see 5 the disclosure form? 6 BY MR. TISI: 7 Q. I don't -- I didn't print -- 8 it came too late last night for me to 9 print at the hotel. 10 But you -- 11 MS. MILLER: You printed the 12 e-mail but you didn't print the 13 disclosure it related to? 14 MR. TISI: Excuse me, 15 Counsel. I did not. 16 MS. MILLER: Okay. I -- 17 MR. TISI: Okay. If you 18 have a copy, you can feel free to 19 show it to her. 20 MS. MILLER: Can I get a 21 copy? 22 MR. TISI: But -- but -- 23 well, we'll go off the record and 24 you can get a copy.</p>
<p style="text-align: right;">Page 191</p> <p>1 Q. That's an e-mail that you 2 drafted on March 21, 2019, which would 3 have been -- I don't know what today's 4 date is. That may have been yesterday. 5 A. Yeah, I've been getting my 6 dates mixed up this week. 7 Q. This is an e-mail disclosing 8 to the FDA that you are an expert for 9 Johnson &amp; Johnson in the talc litigation? 10 A. So the first e-mail I -- is 11 sending an updated disclosure form to the 12 FDA. 13 Q. Right. 14 A. The second e-mail is a 15 response from them asking for 16 clarification or answers to some specific 17 questions. 18 And then the last e-mail is 19 my saying here are my responses. 20 Q. Okay. But -- but is it fair 21 to say that you initially provided a 22 disclosure form to -- for the FDA that 23 did not disclose you were an expert for 24 Johnson &amp; Johnson and that this e-mail</p>	<p style="text-align: right;">Page 193</p> <p>1 MS. MILLER: Okay. Let's go 2 off the record and I'll get a 3 copy. 4 THE VIDEOGRAPHER: Remove 5 your microphones. The time is 6 11:33 a.m. Off the record. 7 (Short break.) 8 THE VIDEOGRAPHER: Okay. We 9 are back on the record. The time 10 is 11:48 a.m. 11 BY MR. TISI: 12 Q. Doctor, we took a quick 13 break so that you could look at some 14 documents. Could you tell us why you 15 amended your FDA form yesterday to 16 indicate that you had done some 17 consulting on the talc litigation with 18 J&amp;J? 19 A. So this is for an FDA panel 20 and they wanted a disclosure. And so the 21 first time that I submitted my disclosure 22 I believe it was January 23rd. I listed 23 Johnson &amp; Johnson and \$12,000. So I 24 looked at the box, it says, "Expert</p>

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<p>1 witness, last 12 months." I saw last 2 12 months. "I appeared for or against 3 the following listed firms/issues." 4 And then I saw amount 5 received. 6 So when I saw that, I was 7 like okay, what they want is in the last 8 12 months any money I got from -- that I 9 actually physically got in the last 10 12 months from doing expert work. And so 11 this was the amount that I had received 12 in the last 12 months. 13 So as part of the, what is 14 this notice called? As part of 15 document -- Exhibit 10, the request was 16 for all disclosures made to the FDA, so I 17 was looking through and trying to find 18 all disclosures. And I -- I am learning 19 through my experience here that I need to 20 understand and look at words much more 21 carefully. And so I re-read this again. 22 And then I saw -- and I am 23 sure I read it the first time. But it 24 just didn't register to me. It says "or</p>	<p>1 ongoing work that I'm doing, Johnson &amp; 2 Johnson talc powder litigation -- that's 3 the issue -- and the amount that I 4 billed. 5 Q. And now I notice that these 6 do not contain -- it's supposed to go 7 back 12 months? 8 A. Yes. 9 Q. They did not contain the 10 Viagra work that you've done? 11 A. There was another 12 confidential document that accompanied 13 this, that I believe the decision was 14 made -- I don't know what the legal terms 15 are. And there was a list of all the 16 companies that they wanted just that 17 information on, if I had any sort of 18 engagement with the companies on that 19 list. 20 Q. Who is they? The FDA? 21 A. The FDA. There was another 22 document that accompanied this that 23 explains sort of, you know, the 24 confidentiality disclosure. It says</p>
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<p>1 under negotiation." 2 And so I started thinking 3 about that, and I thought, well, you 4 know, they probably don't really mean 5 just under negotiation, that probably 6 encompasses ongoing work. 7 So I felt it was prudent to 8 amend my disclosure to the FDA to let 9 them know about the ongoing work for 10 which I had not received any money in the 11 last 12 months. And that is the document 12 that is -- is dated incorrectly. I sent 13 the document on the 20th. 3/21/2019. I 14 had my dates mixed up. 15 In there I went through and 16 another thing I had missed is it said 17 firm/issue. So I -- I thought, well, I 18 better also put the issue -- I -- I 19 missed that too the first time. 20 So you now see it says, 21 "Johnson &amp; Johnson/Zytiga patent 22 (prostate cancer)," the amount received. 23 That did not change. 24 And then I added this</p>	<p>1 confidential on top. And that's why it 2 wasn't shared. 3 And Johnson &amp; Johnson was 4 the only firm that I've done any work 5 with that was on that list. 6 Q. Okay. And so you didn't 7 feel that you needed to indicate that you 8 were an expert witness for the 9 manufacturers in Viagra/Cialis, based 10 upon Number F -- Letter F on this form, 11 that says, "Expert witness last 12 months 12 or negotiation, I appeared for or against 13 the following firms/issues." 14 MR. LOCKE: Objection to 15 form. 16 THE WITNESS: Yes, 17 because -- 18 BY MR. TISI: 19 Q. It doesn't -- it doesn't 20 limit to it on the attached list. It 21 simply says -- 22 A. No, but in the confidential 23 document that wasn't, it said, "Please 24 disclose any" -- "Please disclose for the</p>

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<p style="text-align: right;">Page 198</p> <p>1 firms listed on this list." 2 MS. MILLER: There's a cover 3 memo. I can explain. There's a 4 cover memo. And it said do not 5 disclose. Because it said do not 6 disclose and it wasn't the actual 7 conflicts, we did not produce it. 8 BY MR. TISI: 9 Q. Okay. But can we agree the 10 form doesn't -- the form itself -- the 11 disclosure form doesn't limit -- I mean, 12 I can't test this -- your -- because I 13 can't see the document. 14 But what I'm asking you is, 15 the form itself that's filed doesn't list 16 Viagra/Cialis litigation, does it? 17 A. I mean, as you see on the 18 form there, it is not listed, because 19 again, in the cover letter that went with 20 this, the confidential cover letter that 21 says, "Please disclose any engagement 22 with these specific companies," Lilly was 23 not on that. 24 Q. Okay. Let me ask you -- I'm</p>	<p style="text-align: right;">Page 200</p> <p>1 is a different -- two different things, 2 correct? 3 A. Now I'm confused. I mean -- 4 Q. Okay. Let me -- because I 5 don't want to get -- I don't want to get 6 bogged down. 7 Would you agree with me that 8 these three -- these courses that you 9 taught deal primarily with trial design, 10 statistical methods or biostatistics 11 review? 12 MS. MILLER: Objection. 13 BY MR. TISI: 14 Q. We can argue about whether 15 it's epidemiology or not later. Would 16 you agree that that is the focus? 17 MS. MILLER: Objection. 18 Really try to stick to one 19 question. I'm really pleading 20 with you. 21 MR. TISI: She's looking at 22 me like I've lost my mind. 23 THE WITNESS: Well, no, 24 because, I mean -- I mean -- I</p>
<p style="text-align: right;">Page 199</p> <p>1 going to mark this as 10-E. 2 (Document marked for 3 identification as Exhibit 4 Ballman-10-E.) 5 BY MR. TISI: 6 Q. This is the lectures and 7 workshops on epidemiology. And you wrote 8 epidemiology biostatistics. Is it fair 9 to say that all of these -- all of these 10 have to do with trial designs, 11 statistical methods, or biostatistics? 12 A. So you would say that 13 meta-analyses is not epidemiology? You 14 would say trial design is most 15 epidemiology? I think most 16 epidemiologists would disagree with that. 17 Q. I'm asking you -- there's a 18 difference between trial design and trial 19 analysis and causation analysis, is there 20 not? 21 MS. MILLER: Objection. 22 BY MR. TISI: 23 Q. I mean, doing a study and 24 doing a review of the medical literature</p>	<p style="text-align: right;">Page 201</p> <p>1 mean, clinical trials is 2 epidemiology. It's study design. 3 Biomarker development, that had 4 epidemiology in it because it's 5 very dependent upon study design 6 and what you can say and what you 7 can't say. 8 The trial -- the value of 9 trials, we were talking about 10 meta-analyses. So that -- that, 11 that lecture involved 12 meta-analyses and what a 13 meta-analysis is so forth. As you 14 see in most -- you know, this 15 litigation involves many 16 meta-analyses, and we're calling 17 it epidemiology. 18 BY MR. TISI: 19 Q. I didn't ask you whether -- 20 I simply asked you -- and, you know, 21 forgive me if I think you're being 22 defensive here. 23 MS. MILLER: Objection. 24 BY MR. TISI:</p>

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<p>1 Q. Okay. Okay. Because I've 2 simply asked are these primarily focused 3 on trial design, statistical methods, and 4 biostatistics review. 5 MS. MILLER: Objection. 6 THE WITNESS: I don't know 7 how to answer that because, I 8 mean, that's what the titles say. 9 BY MR. TISI: 10 Q. Thank you. 11 A. But it does not say sort of 12 what the content is of -- 13 Q. I'm going to ask you that 14 question. You really need to -- you 15 really need to answer my question, and 16 then I will ask the follow-up questions. 17 So are these -- the next 18 question that I'm going to ask, do any of 19 these in any of these courses or 20 lectures, did you teach students how to 21 do a Bradford Hill analysis? 22 MS. MILLER: Objection. Is 23 this about courses? I thought it 24 was just lectures.</p>	<p>1 A. Just, just a very vague. 2 Q. What is your understanding? 3 MS. MILLER: Objection. 4 That's a legal question. I don't 5 think that's a question for an 6 expert. That's a question for a 7 lawyer. 8 BY MR. TISI: 9 Q. What is your -- 10 MR. TISI: I understand. 11 BY MR. TISI: 12 Q. What is your understanding? 13 MS. MILLER: She's not an 14 expert on the law -- 15 MR. TISI: I'm asking her 16 what her understanding is. 17 THE WITNESS: I -- 18 MS. MILLER: I understand, 19 but I don't think that's an 20 appropriate question. 21 MR. TISI: Okay. Fine. 22 THE WITNESS: Yeah, I don't 23 even know if I -- I even want to 24 hazard what my understanding is,</p>
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<p>1 MR. TISI: Lectures. In any 2 of these lectures. 3 MS. MILLER: You said 4 courses. 5 THE WITNESS: I don't 6 believe Bradford Hill was 7 mentioned in -- in these 8 particular lectures, no. 9 BY MR. TISI: 10 Q. Okay. Okay. Now before we 11 discuss any further, let me just go back 12 and -- and ask you. 13 The front page of your 14 report talks about general causation 15 Daubert hearings, the page that you 16 signed, correct, on Exhibit 1? 17 A. That's what it says. 18 Q. Okay. And has -- has it 19 been explained to you or do you have any 20 understanding -- let me rephrase the 21 question. 22 Do you have any 23 understanding as to what Daubert hearings 24 are?</p>	<p>1 because that's outside the scope 2 of my expertise. 3 And I -- I've been learning, 4 as I have mentioned, I've been 5 learning through these processes 6 that the words I use are very 7 important. And so I am just not 8 even going to hazard. 9 BY MR. TISI: 10 Q. Whether you -- do you know 11 whether or not in these hearings the 12 question is going to be whether or not 13 the witnesses are qualified? 14 MS. MILLER: Objection. 15 BY MR. TISI: 16 Q. Do you have any 17 understanding of that? 18 MS. MILLER: Objection. 19 Again, that was two questions. I 20 think it's really hard when you 21 ask two questions. I'm sorry to 22 keep repeating this. 23 BY MR. TISI: 24 Q. Do you have -- do you have</p>

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<p>1 any understanding as to one in the issues 2 in the Daubert hearings is whether the 3 witness is qualified to give an opinion 4 on which they are proffered to give an 5 opinion on? 6 A. I -- I -- my understanding 7 is, is experts should be experts in -- in 8 the area that they were retained for. 9 Q. And use a proper 10 methodology, correct? 11 A. Well, if they were experts, 12 I would presume that -- that they use -- 13 they are experts in their area so they 14 know what to do. 15 Q. Do you have any -- 16 MS. MILLER: Objection. 17 BY MR. TISI: 18 Q. And that -- so, you agree 19 with me that being qualified experts in 20 the field, that the plaintiffs' experts 21 as your -- have used a proper 22 methodology, they all looked at Bradford 23 Hill, correct? 24 MS. MILLER: Objection.</p>	<p>1 THE WITNESS: I mean, 2 that -- that's a very vague 3 question. So I -- I can say what 4 I did. I looked at the totality 5 of the evidence using established 6 epidemiology framework, and I came 7 to the conclusion that there is no 8 credible evidence -- 9 BY MR. TISI: 10 Q. Okay. 11 A. -- of a causal association 12 between talc and -- 13 Q. I understand that you -- 14 MR. TISI: Again, she's not 15 answering my question -- 16 MS. MILLER: She still has 17 to -- 18 MR. TISI: No, I understand, 19 but she can't filibuster. 20 BY MR. TISI: 21 Q. I'm -- I didn't ask you what 22 you did. 23 I'm asking you, did the 24 experts when you read their reports on</p>
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<p>1 THE WITNESS: Yeah, that's 2 starting to go beyond my -- my 3 understanding of law. I mean I 4 know that the -- both sides have 5 experts and they -- both sides' 6 experts say what they're experts 7 in, are -- were retained on the 8 basis of what their expertise is, 9 but that -- that's basically all I 10 know. 11 BY MR. TISI: 12 Q. Do you have any reason to 13 believe, based upon -- you may disagree 14 with some of the weights or -- and I 15 think you're pretty clear in your report 16 of some of the criticisms that you have 17 about the way in which certain evidence 18 was looked at by some plaintiffs' 19 experts. Putting aside Smith-Bindman's 20 meta-analysis for a moment. 21 Isn't it fair to say that 22 they applied the same general methodology 23 that you did? 24 MS. MILLER: Objection.</p>	<p>1 the plaintiffs' side, whether you agreed 2 or disagreed with their conclusions, did 3 they use the same framework that you did? 4 MS. MILLER: Objection. 5 THE WITNESS: I -- I can't 6 say that. 7 BY MR. TISI: 8 Q. Okay. 9 A. I mean, I -- I don't know -- 10 Q. And that's fine then. Just 11 answer it that way. 12 A. Okay. I -- I can't say that 13 with certainty. 14 Q. That's fine. 15 Is there any methodologic 16 flaw, apart from you that you gave 17 different -- different weights to the 18 evidence and you looked at the evidence 19 differently, is there any methodologic 20 flaw that you have identified in any of 21 the plaintiffs' experts' reports? 22 MS. MILLER: Objection. Is 23 there a specific expert you're 24 referring to?</p>

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<p>1 MR. TISI: I'm -- if she 2 says yes, I will then go through 3 them. 4 BY MR. TISI: 5 Q. Apart from Smith-Bindman. 6 And I know you have a whole section on 7 Smith-Bindman. 8 A. Well, I -- I also have sort 9 of -- I -- I address other opinions that 10 experts have made and -- and say why I -- 11 I don't believe that the scientific 12 evidence supports what they -- they came 13 to. 14 So obviously, I mean that -- 15 that's -- that I think is part and parcel 16 as to -- 17 Q. But that's a conclusion 18 question, right? So -- so -- 19 MS. SHARKO: You can't 20 interrupt the witness. 21 MR. TISI: You know, she -- 22 MS. MILLER: This is crazy. 23 MR. TISI: All right. You 24 know --</p>	<p>1 I assume your learned 2 counsel here knows how to defend a 3 deposition. Can I assume that? 4 MS. SHARKO: Are we going to 5 take my deposition now? 6 MR. TISI: Well, I mean, 7 unless -- if you want to go under 8 oath I'm happy to ask you 9 questions. 10 MS. SHARKO: Is that a -- 11 MR. TISI: Otherwise -- 12 otherwise, I would appreciate it 13 if you would simply observe. 14 BY MR. TISI: 15 Q. So, Dr. Ballman, have you 16 identified any methodologic -- apart from 17 disagreeing about some of the weights 18 that Dr. Siemiatycki ascribed to certain 19 studies, do you have any criticism of the 20 methodology he used? 21 A. Of what he used in his 22 meta-analyses? 23 Q. In hi -- in any -- in his 24 report, entirely.</p>
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<p>1 MS. MILLER: You've 2 interrupted every sentence that 3 she's given you since we came back 4 from the break and that's just not 5 fair. 6 MR. TISI: I must tell you, 7 you are not going to do this. 8 MS. MILLER: I'm not going 9 to do what? 10 MR. TISI: So -- so -- let 11 me -- let me -- 12 MS. SHARKO: You're not 13 going to do this. 14 MR. TISI: Are we doing one 15 or two now? 16 MS. SHARKO: Mr. Tisi, you 17 can't interrupt the witness. 18 MR. TISI: Okay. 19 MS. SHARKO: You know that, 20 so behave yourself. 21 MR. TISI: We have -- so why 22 don't you switch seats -- you can 23 switch seats and we can go -- 24 we -- we can have one at a time.</p>	<p>1 A. So, I mean, overall, you 2 know, I -- I think that there are flaws 3 in the methodology of all the experts. 4 Q. Okay. Tell me what -- tell 5 me what they are. 6 A. Well, we can go through my 7 report. 8 Q. No, I want you -- you can go 9 through your report. But I -- just give 10 me a general understanding about what 11 your criticism with Dr. Siemiatycki is. 12 MS. MILLER: If you need to 13 look at your report -- 14 THE WITNESS: Yeah, I 15 can't -- 16 MS. MILLER: -- don't let 17 him prevent you from looking at 18 your report. 19 THE WITNESS: Yeah, and I 20 need to -- I need to look at 21 his -- the expert report of 22 Dr. Siemiatycki in order to make 23 sure that -- 24 BY MR. TISI:</p>

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<p>1 Q. As you sit here right now 2 without looking at his report, do you 3 have any criticisms of Dr. Siemiatycki 4 that you can -- that you can articulate 5 for me? 6 MS. MILLER: Objection. 7 That's not fair. The witness said 8 she needs to look at her report. 9 She needs to look at his report. 10 This is not a memory test, is it? 11 MR. TISI: I'm here to take 12 her deposition. 13 BY MR. TISI: 14 Q. So I'd like to know, as you 15 sit here -- I assume you spent time with 16 counsel preparing, correct? 17 A. I would like to see the 18 reports, please, because I don't want to 19 misstate something just because my memory 20 is -- is not well -- doing well right 21 now. 22 Q. So you cannot -- you 23 cannot -- is it fair to say that you 24 cannot offer an opinion as to the</p>	<p>1 so I don't know exactly what I'm going to 2 be questioned on. 3 Q. Okay. Now, you offered an 4 opinion in the Viagra Cialis product 5 liability litigation? 6 A. I did. 7 Q. Like in this case, you were 8 asked by a pharmaceutical company lawyer 9 to testify on issues about whether or not 10 a product causes a disease, correct? 11 MR. LOCKE: Objection. 12 THE WITNESS: In Viagra, I 13 was asked to evaluate the totality 14 of the evidence that exists as to 15 whether or not exposure to Cialis, 16 in particular, I think, because 17 Lilly, I think, is Cialis and not 18 Viagra. 19 Whether or not it causes 20 melanoma. 21 BY MR. TISI: 22 Q. Okay. So the answer to my 23 question is you were asked to look at a 24 general causation question as to whether</p>
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<p>1 methodologic flaws of Jack Siemiatycki 2 without sitting here and going through 3 his report? 4 MS. MILLER: Objection. 5 BY MR. TISI: 6 Q. Because I assumed you would 7 have done that before today. 8 MS. MILLER: Objection. 9 THE WITNESS: I think it's 10 fair to say that I have reviewed 11 many expert reports. I wrote my 12 report. And everything is 13 becoming a jumble. And I just 14 want to make sure that I -- I can 15 refresh my memory in order to 16 render the opinions you're looking 17 for. 18 BY MR. TISI: 19 Q. Do you understand that in a 20 Daubert hearing that you too will be 21 questioned about your -- both your 22 qualifications and your methodology? Do 23 you understand that? 24 A. I -- I -- I'm not a lawyer,</p>	<p>1 or not a product causes a disease? 2 MS. MILLER: Objection. 3 THE WITNESS: I don't 4 know -- 5 MS. MILLER: Please. 6 THE WITNESS: -- that the -- 7 I'm sorry. 8 Can I answer? 9 BY MR. TISI: 10 Q. Please. 11 MS. MILLER: Of course. 12 Just give me time. That's all I'm 13 asking. 14 THE WITNESS: So, I don't 15 know what general causation means. 16 BY MR. TISI: 17 Q. I didn't ask you general 18 causation. 19 A. I thought you did. 20 Q. If I did -- the question was 21 to whether -- 22 MS. MILLER: "So the answer 23 to my question is you were asked 24 to look at a general causation</p>

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<p>1 question." You did say --</p> <p>2 MR. TISI: Well, I wasn't</p> <p>3 talking general causation.</p> <p>4 BY MR. TISI:</p> <p>5 Q. A general question about</p> <p>6 whether or not a product causes a</p> <p>7 disease.</p> <p>8 MS. MILLER: Objection.</p> <p>9 THE WITNESS: Again, I told</p> <p>10 you what I was asked to look for</p> <p>11 there. I was -- and I am giving</p> <p>12 specifics rather than</p> <p>13 generalities. I was asked to look</p> <p>14 at the totality of the</p> <p>15 epidemiology literature as to</p> <p>16 whether or not there is evidence</p> <p>17 that use of Cialis or a PDE5</p> <p>18 inhibitor more generally causes</p> <p>19 melanoma.</p> <p>20 BY MR. TISI:</p> <p>21 Q. Okay. And so you were</p> <p>22 looking about a causation question?</p> <p>23 MS. MILLER: Objection.</p> <p>24 THE WITNESS: Again, I told</p>	<p>1 That was your deposition.</p> <p>2 A. Oh, okay. Okay.</p> <p>3 Q. Okay. Your --</p> <p>4 A. Yeah, the report was</p> <p>5 probably midyear.</p> <p>6 Q. Was the causation --</p> <p>7 causation methodology that you employed</p> <p>8 to look at the question about whether or</p> <p>9 not Cialis was capable of causing</p> <p>10 melanoma the same methodology you used in</p> <p>11 this case?</p> <p>12 A. My general approach was</p> <p>13 similar. I review the data. I -- or the</p> <p>14 literature. I -- I, you know, determine,</p> <p>15 you know, whether or not there appears to</p> <p>16 be evidence of causation using</p> <p>17 established epidemiology principles and I</p> <p>18 come to a conclusion.</p> <p>19 Q. Is there any -- did you</p> <p>20 change your methodology at all between</p> <p>21 Viagra/Cialis and this case. In other</p> <p>22 words, did you use a different -- a</p> <p>23 different standard to evaluate evidence</p> <p>24 or the same standard?</p>
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<p>1 you what I was -- I don't know</p> <p>2 why --</p> <p>3 BY MR. TISI:</p> <p>4 Q. You can't tell me whether or</p> <p>5 not you were looking at a causation</p> <p>6 question in Viagra/Cialis?</p> <p>7 A. I think I answered that. I</p> <p>8 want to be very specific at what I looked</p> <p>9 at.</p> <p>10 Q. And I'm being very -- and</p> <p>11 I'm trying to ask you a question.</p> <p>12 Let me ask you. Let me</p> <p>13 change it.</p> <p>14 Did your talc general</p> <p>15 causation report lay out your</p> <p>16 qualifications -- let me rephrase the</p> <p>17 question.</p> <p>18 Your Viagra/Cialis report</p> <p>19 was issued last year in mid-2018,</p> <p>20 correct?</p> <p>21 A. I believe that's about</p> <p>22 the -- or October maybe. I'm not -- I</p> <p>23 don't know.</p> <p>24 Q. That was your deposition.</p>	<p>1 MS. MILLER: Objection.</p> <p>2 BY MR. TISI:</p> <p>3 Q. In that case as you did</p> <p>4 here?</p> <p>5 MS. MILLER: Sorry. I</p> <p>6 thought you were done. Objection.</p> <p>7 THE WITNESS: I don't know</p> <p>8 what you mean different standard</p> <p>9 versus the same standard.</p> <p>10 Are you talking about did I</p> <p>11 use different words in my report?</p> <p>12 Did I use different --</p> <p>13 BY MR. TISI:</p> <p>14 Q. No. I'm asking whether you</p> <p>15 used the same general framework. For</p> <p>16 example, did you use the Bradford Hill</p> <p>17 framework with respect to Viagra Cialis</p> <p>18 that you used here?</p> <p>19 A. I used established</p> <p>20 epidemiology principles for looking at</p> <p>21 causation, which are based in the</p> <p>22 Bradford Hill criteria.</p> <p>23 Q. Okay. And is there anything</p> <p>24 that you can think of that would be</p>

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<p>1 different -- in other words, if I looked 2 at your Viagra Cialis deposition and your 3 expert report, would it reflect the same 4 methodology that you used here? 5 A. I -- I don't know how you 6 would -- 7 Q. Putting aside the evidence. 8 MS. MILLER: She was in the 9 middle of -- 10 MR. TISI: Well, I -- I -- 11 MS. MILLER: She was 12 literally in the middle of the 13 sentence. I don't think -- 14 MR. TISI: I am going to 15 withdraw the question, Counsel. 16 MS. MILLER: Okay. 17 BY MR. TISI: 18 Q. Okay. Putting aside the 19 fact that the evidence is different -- I 20 mean, obviously it's a different product, 21 different disease here. Putting that 22 issue aside. 23 If the same -- did you apply 24 the same general framework and approach</p>	<p>1 BY MR. TISI: 2 Q. Okay. And is there any 3 difference that you can think of in the 4 approach that you made in Viagra-Cialis 5 than you did here? 6 A. I -- I'm not sure what 7 you're looking for. I have my -- 8 Q. I'm not looking for 9 anything. I'm just looking to say, if 10 you were giving a lecture to -- to 11 students and say, you know, in both of 12 these I use the same -- you know, this is 13 how you do it. For example, in 14 Viagra-Cialis I did it the same way I did 15 it in the talc litigation. 16 MS. MILLER: Objection. 17 BY MR. TISI: 18 Q. Did you do it the same? 19 A. Again, I said I reviewed the 20 literature, I applied Bradford Hill 21 criteria as the basis as to determining 22 whether or not there is causality, and I 23 rendered an opinion. 24 Q. Was the description of the</p>
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<p>1 in looking at the causation question in 2 Viagra/Cialis as you did here? 3 MS. MILLER: Same 4 objections. 5 THE WITNESS: So, as I 6 explained, I -- I -- and I don't 7 know how to explain it any 8 differently. 9 So I -- I looked at all the 10 available evidence that was in the 11 literature. I used the Bradford 12 Hill criteria as the basis for 13 looking at whether or not there 14 was causation, and then I -- I 15 rendered sort of what I -- what my 16 opinion was. 17 BY MR. TISI: 18 Q. And that is the -- that is 19 the standard epidemiologic methodology, 20 true? 21 MS. MILLER: Objection. 22 THE WITNESS: I think it's 23 an accepted epidemiological -- or 24 epidemiologic methodology.</p>	<p>1 methodology you used in Viagra-Cialis 2 truthful? 3 MS. MILLER: Objection. Do 4 you want to put in front of her -- 5 MR. TISI: No, I don't. 6 MS. MILLER: But that's not 7 fair. 8 MR. TISI: I asked her -- 9 MS. MILLER: You are turning 10 this deposition into a memory 11 test. 12 MR. TISI: Counsel. 13 Counsel, this is not a memory 14 test. 15 MS. MILLER: Okay. 16 BY MR. TISI: 17 Q. Did you -- is there 18 anything -- have you re-read your 19 deposition in Viagra-Cialis? 20 A. My deposition? 21 Q. Mm-hmm. 22 A. No. 23 Q. Do you know that there's -- 24 A. Well, the deposition?</p>

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<p>1 Q. Mm-hmm. 2 A. In Viagra-Cialis? 3 Q. Mm-hmm. 4 A. I've read parts of it, yes. 5 Q. Okay. Do you know that 6 there's a Daubert challenge to you in 7 Viagra-Cialis? 8 A. Yes, I am aware of that. 9 Q. Okay. And you know that the 10 hearing is in June, correct? 11 A. No, I didn't know that. 12 Q. Okay. Have you not been 13 told that there's a hearing set? 14 A. No, I have not been told 15 that. 16 Q. And is there anything about 17 your approach in Viagra-Cialis as a 18 result of re-reading your testimony that 19 you would change about your approach that 20 you did it here? 21 A. No. 22 MS. MILLER: Objection. 23 BY MR. TISI: 24 Q. Okay. So that --</p>	<p>1 MS. MILLER: Okay. Go 2 ahead. 3 BY MR. TISI: 4 Q. Would you agree that -- 5 you've testified to this before, sort of 6 about epidemiology and biostatistics. 7 While there's some overlap obviously 8 between biostatistics and epidemiology, 9 you've pointed that out. And these are 10 related fields, that they are two 11 distinct scientific disciplines? 12 A. I think, as I mentioned, 13 that at the basic level, the overlap is 14 almost complete between epidemiology and 15 biostatistics. 16 Q. Okay. 17 A. So Epi 101 and Biostats 101 18 are -- are very, very similar. If you 19 would look at table of contents of books 20 they would have similar concepts being -- 21 being taught. 22 I would also say that within 23 clinical research the overlap between 24 epidemiology and biostatistics is very</p>
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<p>1 MS. MILLER: Please try to 2 remember to leave me time to 3 object, please. 4 BY MR. TISI: 5 Q. Would you -- 6 MS. MILLER: You two are 7 talking over each other and I'm 8 not having an opportunity to 9 object properly. 10 I want the record to show my 11 objection before your answer. 12 MR. TISI: How about if I 13 just agree that you object to 14 every question and we can move on? 15 MS. MILLER: How about we 16 just agree that you start asking 17 unobjectionable questions? It 18 would be so much smoother -- 19 MR. TISI: I am so happy -- 20 MS. MILLER: -- and the depo 21 would go so much quicker. 22 MR. TISI: -- I will submit 23 every question I have to the 24 court.</p>	<p>1 complete. 2 I would also say that 3 epidemiology as a field has other areas 4 that aren't so overlapped with 5 biostatistics, such as public health. 6 That -- that is a pure epi sort of topic. 7 Within biostats, there are 8 areas in biostats that are not that 9 overlapping with epidemiology. It's the 10 area where people want to develop new 11 mathematical techniques and so that's 12 almost more overlapping with mathematics 13 because of the theory beneath it. 14 And so I, as a clinical 15 research in my career over the last 16 20-some years, sits right in that really 17 overlapped area. And so that's what -- 18 what I do. 19 Q. Okay. Let me -- let me move 20 to strike the answer because it wasn't -- 21 that wasn't my question. 22 My question was, would you 23 agree -- let me -- me give you a 24 different question.</p>

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<p>1 Would you agree that being 2 an epidemiologist does not automatically 3 qualify a professional as a statistician 4 or biostatistician? 5 MS. MILLER: Objection. 6 THE WITNESS: I -- I'm not 7 sure what exactly you're -- you're 8 asking there. 9 BY MR. TISI: 10 Q. Has every -- can every 11 epidemiologist do what you do? 12 A. I -- I would have to see 13 what the particular epidemiologist -- 14 Q. I'm not asking that -- 15 A. -- the experience and 16 training is in order to -- 17 Q. Because -- because they are 18 distinct fields, true? 19 There is overlap, just like 20 cardiology and cardiac surgery, overlap, 21 right? 22 MS. MILLER: Objection. 23 She's -- 24 BY MR. TISI:</p>	<p>1 MS. MILLER: Objection. 2 What do you mean by her website? 3 MR. TISI: Can we have the 4 next exhibit, please. Exhibit 11. 5 (Document marked for 6 identification as Exhibit 7 Ballman-11.) 8 BY MR. TISI: 9 Q. This is your website from 10 Weill Cornell? 11 A. I -- I don't know if it's my 12 website. I believe it's the division's 13 website of biostatistics and 14 epidemiology. 15 Q. It has your picture on it? 16 A. Well, it has my picture on 17 it, but it says biostatistics and 18 epidemiology. It doesn't say Karla 19 Ballman at the top. 20 Q. Actually it says, "Weill 21 Cornell Medical Center Biostatistics and 22 Epidemiology," correct? 23 A. Way at the top, yes. 24 Q. Right. And underneath your</p>
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<p>1 Q. Epidemiology and 2 biostatistics overlap, true? 3 MS. MILLER: That's three 4 questions. I'm looking at the -- 5 BY MR. TISI: 6 Q. I'm asking you the question: 7 Do epidemiology and biostatistics 8 overlap? 9 A. They overlap considerably in 10 some areas. 11 Medicine and epidemiology 12 overlap. There are medical doctors that 13 do epidemiology. But medicine is very 14 different and distinct discipline from 15 epidemiology. 16 Q. Is epidemiology concerned 17 with the distribution causation and 18 control of disease across time and space 19 and human populations? 20 A. I believe that's one 21 definition that one could use. 22 Q. In fact, that's the 23 definition on your website, is it not? 24 A. It may well be.</p>	<p>1 picture it says Dr. Karla Ballman? 2 A. Yes, that's correct. 3 Q. And underneath that it has 4 two separate definitions, one for 5 biostatistics and one for epidemiology, 6 correct? 7 A. Yeah, that's what's there. 8 Q. "Epidemiology says it's 9 concerned with the distribution, 10 causation, and control of disease across 11 time and space in human population." 12 Do you see that? 13 A. Yes, that's what's written 14 there, yes. 15 Q. Okay. And underneath -- 16 above that is a section that says, 17 "Biostatistics is the application of 18 statistical techniques to scientific 19 research in health-related fields 20 including medicine, biology, and public 21 health in the development of novel 22 methodologies that could improve the 23 application. Since the beginning of the 24 Twentieth Century, the field of</p>

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<p style="text-align: right;">Page 234</p> <p>1 biostatistics has become an in 2 dispensable tool in improving health and 3 reducing illness." 4 Correct? 5 A. What you read there is what 6 it states. I mean, I'll point out that's 7 this is a biostatistics -- 8 Q. That's all I asked. 9 A. -- and epidemiology 10 department -- 11 Q. All I asked is whether I 12 read it correctly. 13 A. You did read it correctly. 14 Q. Thank you. This is your 15 website for your department, correct? 16 A. So I don't think you're 17 letting me sort of address what you're 18 trying to imply. 19 Q. I'm not trying to imply 20 anything. 21 MS. MILLER: Please, let her 22 answer. 23 MR. TISI: No, the problem 24 is -- I think her answer really</p>	<p style="text-align: right;">Page 236</p> <p>1 definitions, one for biostatistics and 2 one for epidemiology, correct? 3 MS. MILLER: Objection. 4 THE WITNESS: It has -- it 5 has two statements there. One for 6 biostatistics and one for 7 epidemiology. And then it has, 8 "The mission of the division of 9 biostatistics and epidemiology." 10 And that's not -- that's the 11 mission of our division -- 12 MR. TISI: Counsel -- 13 THE WITNESS: -- which is to 14 develop epidemiologic studies in 15 the fields of hypertension, 16 women's health, perioperative -- 17 MR. TISI: -- honestly can 18 you just ask your witness to 19 answer the question. 20 THE WITNESS: -- outcomes and 21 anesthesiology. And that is 22 actually quite outdated because we 23 do more than that. 24 MR. TISI: Okay. Okay.</p>
<p style="text-align: right;">Page 235</p> <p>1 illustrates the problems here. 2 She's anticipating where she 3 thinks that I'm going. I'm asking 4 her very straightforward 5 questions. 6 BY MR. TISI: 7 Q. The question is, is this 8 your department's web page? 9 A. Yes. 10 MS. MILLER: I think you 11 know the answer to that. So 12 that's -- 13 MR. TISI: Okay. Well, I 14 have to put it on the record, 15 Counsel. 16 BY MR. TISI: 17 Q. Is it your department's web 18 page? 19 A. I believe it is. I haven't 20 been out at that web page in -- I don't 21 know when. So if you say this is what 22 you got from our -- as our division's web 23 page, I will take that as your word. 24 Q. And it has two separate</p>	<p style="text-align: right;">Page 237</p> <p>1 Counsel, I'm really going to ask 2 you, maybe we can take a break and 3 you can ask your witness to answer 4 the question. 5 BY MR. TISI: 6 Q. I'm simply asking, are there 7 two separate definitions on this page? 8 MS. MILLER: You've asked 9 that three times. 10 MR. TISI: Well, but I'm not 11 getting an answer. She wants to 12 go and read the rest of the 13 document. 14 MS. MILLER: You said it 15 has -- she did answer. "It has 16 two separate definitions" -- 17 MR. TISI: And she goes on. 18 MS. MILLER: -- "one for 19 biostatistics and one for 20 epidemiology, correct?" And she 21 says, "It has two statements 22 there, one for biostatistics and 23 one for epidemiology. And then it 24 has the mission of division of</p>

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<p>1 biostatistics" --</p> <p>2 MR. TISI: Did I ask her</p> <p>3 that? Did I ask her about the</p> <p>4 mission?</p> <p>5 MS. MILLER: Did she not</p> <p>6 answer your question, sir?</p> <p>7 MR. TISI: Yes, but then she</p> <p>8 goes on a speech.</p> <p>9 MS. MILLER: You are pulling</p> <p>10 statements out of context --</p> <p>11 MR. TISI: I'm not pulling</p> <p>12 it out of context.</p> <p>13 MS. MILLER: -- and she's</p> <p>14 providing some context. She's</p> <p>15 providing the context --</p> <p>16 MR. TISI: Counsel.</p> <p>17 Counsel.</p> <p>18 MS. MILLER: Why are you</p> <p>19 yelling at me?</p> <p>20 MR. TISI: Because I think</p> <p>21 this is bizarre.</p> <p>22 MS. MILLER: Really? I</p> <p>23 think you're --</p> <p>24 MR. TISI: I simply asked</p>	<p>1 Q. These are two separate --</p> <p>2 these are two separate statements by</p> <p>3 biostatistics and epidemiology, true?</p> <p>4 MS. MILLER: Objection.</p> <p>5 Asked and answered four times or</p> <p>6 five.</p> <p>7 BY MR. TISI:</p> <p>8 Q. Are they separate</p> <p>9 statements?</p> <p>10 A. They are separate</p> <p>11 statements.</p> <p>12 Q. Thank you.</p> <p>13 A. Because --</p> <p>14 MS. MILLER: Finish your</p> <p>15 sentence if you'd like to.</p> <p>16 THE WITNESS: Well, they are</p> <p>17 separate statements, because it</p> <p>18 says biostatistics and</p> <p>19 epidemiology on top. So, I mean,</p> <p>20 why wouldn't you have sort of two</p> <p>21 separate, you know --</p> <p>22 BY MR. TISI:</p> <p>23 Q. I am not asking why you</p> <p>24 would. I'm just asking whether you do.</p>
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<p>1 are there two definitions on the</p> <p>2 page, one for epidemiology. I did</p> <p>3 not ask anything about the mission</p> <p>4 of the department, did I?</p> <p>5 MS. MILLER: She answered</p> <p>6 your question.</p> <p>7 THE WITNESS: Actually, can</p> <p>8 I -- can I. You said two</p> <p>9 definitions. And I said -- I</p> <p>10 think I said two statements. It</p> <p>11 nowhere here says these are</p> <p>12 definitions.</p> <p>13 BY MR. TISI:</p> <p>14 Q. Okay.</p> <p>15 A. These are just descriptions,</p> <p>16 and it's not a definition. And -- okay.</p> <p>17 Q. I'll let -- I'll let -- I'll</p> <p>18 let the judge and jury decide whether or</p> <p>19 not these are definitions when it says</p> <p>20 "biostatistics is" and "epidemiology is."</p> <p>21 We'll let them decide that.</p> <p>22 MS. MILLER: What jury are</p> <p>23 you talking about?</p> <p>24 BY MR. TISI:</p>	<p>1 A. Yeah, there are two</p> <p>2 separate --</p> <p>3 Q. Perfect.</p> <p>4 A. -- descriptions.</p> <p>5 Q. Perfect. Now, the next</p> <p>6 question is, there are people within your</p> <p>7 department who actually do have degrees</p> <p>8 in epidemiology, true?</p> <p>9 A. I know of one. Can you name</p> <p>10 several more?</p> <p>11 Q. Dr. Drusin. He's a medical</p> <p>12 doctor with a degree in epidemiology?</p> <p>13 A. He is adjunct -- he is in my</p> <p>14 department -- my division I think. But</p> <p>15 it's unclear as to whether he belongs</p> <p>16 there, because we had a whole -- had a</p> <p>17 whole restructure of our department a</p> <p>18 while ago. And there were other</p> <p>19 divisions, and he belonged to a different</p> <p>20 division and got put into my --</p> <p>21 Q. Does Dr. Gerber have a Ph.D.</p> <p>22 in epidemiology?</p> <p>23 A. She does have a Ph.D. in</p> <p>24 epidemiology and does -- and we talked</p>

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<p>1 about her work --</p> <p>2 Q. I just asked you whether she</p> <p>3 had it. That's all. Simple question.</p> <p>4 A. Okay. I'm just trying to</p> <p>5 say that she feels she's more of a</p> <p>6 biostatistician.</p> <p>7 Q. I'm not asking what she</p> <p>8 feels, Doctor. I really am asking you,</p> <p>9 does she have a degree in epidemiology.</p> <p>10 A. She has a degree in</p> <p>11 epidemiology.</p> <p>12 Q. Does Dr. -- does Professor</p> <p>13 Christos have a master's in epidemiology?</p> <p>14 A. I don't know. I believe</p> <p>15 it's in public health.</p> <p>16 Q. Okay.</p> <p>17 A. Which is different from</p> <p>18 epidemiology --</p> <p>19 Q. Now --</p> <p>20 A. -- in the same way as</p> <p>21 statistics -- a lot of overlap, like with</p> <p>22 biostatistics.</p> <p>23 Q. Doctor, I'm going to show</p> <p>24 you what's marked as Exhibit Number 12.</p>	<p>1 A. You read that correctly.</p> <p>2 Q. Would you please go to the</p> <p>3 next page and look down the page, and</p> <p>4 when you were asked that question, what</p> <p>5 did you say?</p> <p>6 A. So -- and I believe I</p> <p>7 answered this before.</p> <p>8 Q. I'm just asking what you</p> <p>9 said. Would you read into the record</p> <p>10 what you said.</p> <p>11 A. I will. I will.</p> <p>12 Q. Thank you.</p> <p>13 A. And again, I'm just</p> <p>14 reiterating that this is --</p> <p>15 Q. You don't need to reiterate.</p> <p>16 I'm just simply asking you what you said.</p> <p>17 A. So it says, "I'm Karla</p> <p>18 Ballman. I'm the division chief of</p> <p>19 biostatistics and epidemiology at Weill</p> <p>20 Cornell Medicine in New York City, and</p> <p>21 obviously I'm a statistician."</p> <p>22 Q. Thank you.</p> <p>23 A. Let me point out that there</p> <p>24 are others here who also have MPH</p>
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<p>1 This will be very quick.</p> <p>2 (Document marked for</p> <p>3 identification as Exhibit</p> <p>4 Ballman-12.)</p> <p>5 BY MR. TISI:</p> <p>6 Q. This is a portion of a</p> <p>7 transcript from the Center For Devices</p> <p>8 and Radiologic Health Medical Advisory</p> <p>9 Committee that you sat on in June of</p> <p>10 2018.</p> <p>11 Do you see that?</p> <p>12 A. Well, I -- I see the</p> <p>13 document that you handed me, yes.</p> <p>14 Q. And in the -- on Page 7 it</p> <p>15 says, from Dr. Nathan, it says -- fourth</p> <p>16 paragraph down, "Before we begin, I'd</p> <p>17 like to ask our distinguished panel</p> <p>18 members and FDA staff seated at this</p> <p>19 table to introduce themselves. Please</p> <p>20 state your name, your area of expertise,</p> <p>21 your position, and your affiliation.</p> <p>22 We'll go counterclockwise and start with</p> <p>23 Ms. Barnes."</p> <p>24 Do you see that?</p>	<p>1 degrees, and they identify themselves as</p> <p>2 doctors.</p> <p>3 So again it depends upon</p> <p>4 what role you play within these</p> <p>5 committees.</p> <p>6 Q. Doctor, you are a member of</p> <p>7 SARC, what is SARC?</p> <p>8 A. SARC is the -- is a</p> <p>9 nonprofit organization that does research</p> <p>10 in sarcoma.</p> <p>11 Q. Okay. And there's a web</p> <p>12 page for you on SARC.</p> <p>13 (Document marked for</p> <p>14 identification as Exhibit</p> <p>15 Ballman-13.)</p> <p>16 BY MR. TISI:</p> <p>17 Q. Exhibit Number 13.</p> <p>18 Does it identify you as</p> <p>19 statistician at the top?</p> <p>20 A. It does say statistician at</p> <p>21 the top. But it says I'm professor of</p> <p>22 biostatistics in the division of Weill</p> <p>23 Cornell biostatistics and epidemiology.</p> <p>24 "She is a recognized expert in cancer</p>

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<p>1 research study design and analyses for 2 clinical trials." 3 There's that overlap again 4 with epidemiology. 5 Q. Does it say anything about 6 causation there? 7 MS. MILLER: Objection. 8 BY MR. TISI: 9 Q. To say I'm an expert in 10 analyzing whether or not substances cause 11 disease? 12 MS. MILLER: Objection. 13 THE WITNESS: That -- that's 14 very specific. 15 Let me say that if you -- 16 BY MR. TISI: 17 Q. Does it say that there? 18 MS. MILLER: Objection. 19 THE WITNESS: Well, it 20 doesn't say that there, but -- 21 BY MR. TISI: 22 Q. Thank you. 23 A. -- it doesn't say many 24 things that -- that I do.</p>	<p>1 Q. This is the website of the 2 American Statistical Association. And it 3 says the -- it says, "The American 4 Statistical Association is the world's 5 largest community of statisticians. The 6 Big 10 for statistics." 7 Do you see that? 8 A. Yeah. I -- I just don't 9 know. This is -- I -- I don't know where 10 you pulled this off from the ASA. So I 11 mean, that's what it says on this 12 particular page. 13 Q. And it has a directory, if 14 you go to the last page, and you are 15 listed as a consultant. 16 Do you see that? 17 A. Yes, I see that. 18 Q. It has your phone number and 19 your e-mail address and all the 20 information? 21 A. Yeah, mm-hmm. 22 Q. Okay. Could you read -- 23 read for the record what you identified 24 to your colleagues as your areas of</p>
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<p>1 Q. Are you a member of the -- 2 what's known as the American Statistical 3 Association? 4 A. I am. 5 Q. What is the American 6 Statistical Association? 7 A. It's the American 8 Statistical Association. 9 Q. Is it a reputable 10 organization of statisticians? 11 MS. MILLER: Objection. 12 THE WITNESS: And 13 epidemiologists. 14 BY MR. TISI: 15 Q. Okay. And -- and 16 epidemiologists. Okay. 17 And the American Statistical 18 organization, is -- and I'm going to have 19 this marked as exhibit -- what is this, 20 Exhibit 14? 21 (Document marked for 22 identification as Exhibit 23 Ballman-14.) 24 BY MR. TISI:</p>	<p>1 expertise? 2 A. Biometrics, and 3 biostatistics, and -- and data collection 4 procedures, operations research, and 5 statistical training. 6 Q. Anything else? 7 A. Well, I just want to point 8 out that again data collection procedures 9 is -- is an area of epidemiology, and 10 biometrics and biostatistics, as I said, 11 also have considerable overlap with 12 epidemiology. 13 Q. By the way, the American -- 14 you were an officer in the American 15 Statistical Association, I think you 16 said? 17 A. Did I say that? 18 Q. I think it's in your -- I 19 think it's in your CV, your CV. 20 A. I'll have to look at my CV. 21 But I -- I did play some roles in there 22 at some point. 23 Q. They were volunteer roles, 24 right?</p>

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<p>1 A. They were volunteer roles.</p> <p>2 Q. Have you ever -- do you know</p> <p>3 what it takes to be a fellow at the</p> <p>4 American Statistical Association?</p> <p>5 A. No, I do not.</p> <p>6 Q. Okay. Do you know that they</p> <p>7 have a fellow program where colleagues</p> <p>8 have -- can nominate people with</p> <p>9 distinguished careers in statistics for</p> <p>10 membership in their organization?</p> <p>11 A. I --</p> <p>12 MS. MILLER: She just said</p> <p>13 she doesn't know what it is.</p> <p>14 MR. TISI: Then let's mark</p> <p>15 it.</p> <p>16 THE WITNESS: Well, I -- I</p> <p>17 don't know the specifics of it.</p> <p>18 But I -- I believe that's the</p> <p>19 purpose of -- and most fellowships</p> <p>20 in any profession have that.</p> <p>21 (Document marked for</p> <p>22 identification as Exhibit</p> <p>23 Ballman-15.)</p> <p>24 BY MR. TISI:</p>	<p>1 three-page exhibit. But the first</p> <p>2 two pages are Page 1 of 2 and the</p> <p>3 last one is Page 2 of 2.</p> <p>4 Do you want me to pull out</p> <p>5 this so that it's an accurate</p> <p>6 exhibit?</p> <p>7 MR. TISI: That's fine.</p> <p>8 Thank you.</p> <p>9 MS. MILLER: So here we go.</p> <p>10 I've pulled out the middle page,</p> <p>11 and now we have Page 1 of 2 and</p> <p>12 Page 2 of 2.</p> <p>13 BY MR. TISI:</p> <p>14 Q. Okay. Have you ever been</p> <p>15 nominated as an ASA fellow, do you know?</p> <p>16 A. I have no idea.</p> <p>17 Q. Okay. Have you -- are --</p> <p>18 you are not an ASA fellow, are you?</p> <p>19 A. I am not an ASA fellow.</p> <p>20 Q. Okay. And to be clear, an</p> <p>21 ASA fellow would be somebody whose</p> <p>22 contribution to the advancement of</p> <p>23 statistical science and places due weight</p> <p>24 on public works, positions held with</p>
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<p>1 Q. I'm going to -- yeah.</p> <p>2 Other than my -- and I -- I</p> <p>3 sent this to my e-mail address, and I</p> <p>4 apologize.</p> <p>5 But other than that, this is</p> <p>6 a list from the website from the ASA.</p> <p>7 A. Mm-hmm.</p> <p>8 MR. TISI: I only have one</p> <p>9 copy I printed out this morning,</p> <p>10 I'm sorry, Counsel, if you would</p> <p>11 share it.</p> <p>12 BY MR. TISI:</p> <p>13 Q. It says, "A designation of</p> <p>14 an ASA fellow has been a significant</p> <p>15 honor for nearly 100 years. People</p> <p>16 can" --</p> <p>17 MS. MILLER: Actually isn't</p> <p>18 every page the same?</p> <p>19 THE WITNESS: Oh yeah.</p> <p>20 MR. TISI: Maybe it is. I</p> <p>21 apologize.</p> <p>22 MS. MILLER: Wait, this is</p> <p>23 confusing. I just want to state</p> <p>24 for the record that this is a</p>	<p>1 employer, ASA activities, membership and</p> <p>2 accomplishments in societies, and</p> <p>3 professional activities.</p> <p>4 And you are not -- you</p> <p>5 have -- you are not a fellow, correct?</p> <p>6 MS. MILLER: Objection.</p> <p>7 THE WITNESS: I am not.</p> <p>8 MS. MILLER: Please.</p> <p>9 THE WITNESS: You read that</p> <p>10 correctly. I am not a fellow.</p> <p>11 BY MR. TISI:</p> <p>12 Q. In applying for funds --</p> <p>13 actually let me stop for a second.</p> <p>14 You know, from time to time</p> <p>15 the ASA issues statements about</p> <p>16 statistical issues?</p> <p>17 A. I'm vaguely aware that they</p> <p>18 issue statements from time to time.</p> <p>19 Q. Okay. In your CV you</p> <p>20 identify past or present current grants.</p> <p>21 Have you -- do you know if whether you</p> <p>22 have ever asked for a -- identified</p> <p>23 yourself as an epidemiologist by title,</p> <p>24 as an epidemiologist, not as part of your</p>

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<p>1 department? 2 MS. MILLER: Objection. 3 BY MR. TISI: 4 Q. As you are describing 5 yourself, in a -- in a grant that you 6 have ever given for any purpose? 7 MS. MILLER: You just kicked 8 me. Objection. 9 MR. TISI: I apologize. 10 THE WITNESS: I -- I have 11 been on so many grant and grant 12 applications that I cannot off the 13 top of my head tell you whether or 14 not I have ever said I am an 15 epidemiologist. 16 BY MR. TISI: 17 Q. Have you ever to your 18 knowledge ever stood up in a public 19 meeting and said, "I, Karla Ballman, is 20 an -- I am an epidemiologist"? 21 MS. MILLER: Objection. 22 BY MR. TISI: 23 Q. Like you did before, and 24 say, "I'm a statistician"?</p>	<p>1 A. I have been to many 2 professional and public meetings, I don't 3 know if I've ever stood up and said with 4 certainty -- I cannot answer if I've ever 5 stood up and said that. 6 I do have to say that when 7 people hear biostatistics and clinical 8 research, they intertwine epidemiology 9 and biostatistics, so -- 10 Q. But you have never 11 represented to your colleagues 12 affirmatively, "I, Karla Ballman, an 13 epidemiologist"? 14 MS. MILLER: Objection. 15 THE WITNESS: Again, in 16 situations and studies I'm in, by 17 saying a biostatistics and knowing 18 that I do cancer research, they 19 know what that means and they know 20 it involves study design. As you 21 can look in my CV, I have many 22 case-control -- I've done 23 case-control studies. I've done 24 cohort studies. I've done --</p>
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<p>1 MS. MILLER: Objection. 2 BY MR. TISI: 3 Q. Have you ever told your 4 colleagues, "I am an epidemiologist"? 5 MS. MILLER: It's really 6 hard, because I don't know when 7 your question ends. Because you 8 ask a question, and then I object, 9 and then you keep going. 10 MR. TISI: Okay. Fine. I'm 11 sorry. 12 MS. MILLER: It's a very 13 complicated -- 14 MR. TISI: I'm sorry it's 15 hard. 16 MS. MILLER: -- record. But 17 it's not fair to the witness, 18 because I don't -- do you know 19 what question -- 20 THE WITNESS: I'll -- 21 BY MR. TISI: 22 Q. Have you ever stood up in a 23 public professional meeting and said, "I, 24 Karla Ballman, an epidemiologist"?</p>	<p>1 BY MR. TISI: 2 Q. Okay. Your department, your 3 department offers a two-month review 4 course in epidemiology, taught by 5 Dr. Christos. Do you know that? In 6 October/November of every year? 7 A. Is it called a review 8 course? 9 Q. Yes. 10 A. I'm just having some -- and 11 can I see where you are getting at and 12 what it is? 13 Q. Exhibit 16. 14 A. I just want to see what 15 program it's a part of. I'm not 16 disputing that. 17 (Document marked for 18 identification as Exhibit 19 Ballman-16.) 20 THE WITNESS: Is it part of 21 the CTSC program? 22 MR. TISI: Honestly, I've 23 got to -- I thought it was here. 24 BY MR. TISI:</p>

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<p style="text-align: right;">Page 258</p> <p>1 Q. This is Exhibit Number 17, 2 which is the list of courses that I got 3 from the Weill Cornell website. 4 A. I see, okay. 5 Q. Do you see where I'm 6 referring to? 7 A. Are you -- go ahead. Ask 8 your question. I'll let you say it. 9 MS. MILLER: This is 17. 10 Catherine saying she says that she 11 doesn't believe there's a 16, that 12 you went from 15 to 17. Is that 13 correct? 14 MR. SOILEAU: He referenced 15 a 16, but then essentially 16 withdrew it and moved to a new 17 document and marked it as 17. 18 MR. TISI: So why don't we 19 mark it as 16. 20 MS. MILLER: Why don't we 21 mark it 16 for clarity going 22 forward. Thank you, Catherine. 23 BY MR. TISI: 24 Q. So to be clear, this is the</p>	<p style="text-align: right;">Page 260</p> <p>1 Q. I'm asking with -- the title 2 of the course. I'm not asking the 3 content now. So you made that very 4 clear, that it overlaps, and the record 5 is clear on that. 6 I'm asking you have you ever 7 taught a course with the word 8 "epidemiology" in it? 9 A. I do not believe I've taught 10 a course with epidemiology in it. Most 11 of those courses would be intro courses, 12 and when I teach intro courses, I come at 13 it and teach it from the biostats side. 14 That includes epidemiology as a part of 15 it. But I have not taught an 16 epidemiology 101 course. No, I've not 17 had a course with epidemiology in the 18 title. 19 Q. In fact -- in fact, the only 20 two courses that you taught at Cornell 21 Weill are introduction to biostatistics 22 and biostatistics 1? 23 A. I'm trying to remember the 24 titles. And, again, I don't know where</p>
<p style="text-align: right;">Page 259</p> <p>1 list of courses that are offered by the 2 Weill Cornell Medical Center in 3 biostatistics and epidemiology? 4 A. I don't know. Because Madhu 5 Mazumdar who is listed there, that was 6 the individual I replaced. So I don't 7 know where -- I mean, his is not 8 reflective of anything we're -- 9 Q. You see the date on top is 10 three -- March 2019. I mean, it's off 11 the website. I don't know what to tell 12 you, other than that's where I got it. 13 A. Yeah, I agree. I don't know 14 what to tell you either. But that just 15 shows you that we don't keep our website 16 up to date. But Madhu Mazumdar has not 17 been at Weill Cornell for almost four 18 years, if not more than four years so. 19 Q. Let me ask you this. Have 20 you ever taught a course with the word 21 "epidemiology" in it? 22 MS. MILLER: Objection. In 23 the course or in the course -- 24 BY MR. TISI:</p>	<p style="text-align: right;">Page 261</p> <p>1 you're getting that information from. So 2 I want to make sure the titles are 3 correct. 4 MS. MILLER: Is that in your 5 CV? 6 MR. TISI: It is. 7 THE WITNESS: Okay. If it's 8 in my CV. Thank you. And if -- I 9 have only taught two courses. I 10 am not quibbling about that. 11 BY MR. TISI: 12 Q. Thank you. 13 A. I'm just trying to see, you 14 know, if it says intro to biostats or -- 15 okay. Yeah one is part of the executive 16 MBA/MS program. And the other is part of 17 our biostatistics and data science 18 program. Those are two courses that I 19 have taught at Weill Cornell. 20 Q. Does Weill Cornell offer a 21 Ph.D. or an MPH in epidemiology? 22 A. Weill Cornell itself? 23 Q. Mm-hmm. 24 A. No, it does not.</p>

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<p style="text-align: right;">Page 262</p> <p>1 Q. Does -- and Cornell only 2 offers epidemiology as a minor, correct? 3 A. I -- I couldn't comment on 4 that. I don't know what the main campus 5 offers. 6 MS. MILLER: Were you asking 7 Cornell, as in not Weill Cornell 8 but undergraduate? You said -- as 9 in undergraduate courses? 10 MR. TISI: I said in 11 Cornell, regular Cornell, the 12 Cornell upstate in Ithaca. 13 BY MR. TISI: 14 Q. To be clear, you have no 15 publications on ovarian cancer, correct? 16 MS. MILLER: Objection. 17 Asked and answered. 18 THE WITNESS: I have no 19 publications that have -- I 20 believe, that are on ovarian 21 cancer. 22 BY MR. TISI: 23 Q. Any publications on the risk 24 factors for ovarian cancer?</p>	<p style="text-align: right;">Page 264</p> <p>1 A. But the -- 2 Q. But let's let -- 3 MS. MILLER: That's not what 4 he said. 5 THE WITNESS: He didn't say 6 the methodology differed. 7 MR. TISI: Let's -- let's 8 move on. 9 THE WITNESS: He said the 10 individual risk factors differed 11 is my understanding. 12 MS. MILLER: She said in 13 terms of how one would evaluate 14 factors. You're mischaracterizing 15 her testimony. 16 BY MR. TISI: 17 Q. Are there any publications 18 on your CV related to talc? 19 A. No, there are not. 20 Q. Any publications even 21 mention talc and cancer in the same 22 article? 23 MS. MILLER: Objection. 24 We've been through this.</p>
<p style="text-align: right;">Page 263</p> <p>1 MS. MILLER: Objection. 2 THE WITNESS: Again, I just 3 said I have no publications in 4 ovarian cancer. I have 5 publications on -- that evaluate 6 risk factors for many other 7 cancers. 8 BY MR. TISI: 9 Q. But not ovarian? 10 A. Not ovarian, per se, but 11 ovarian cancer is not any different from 12 other cancers in terms of how one would 13 evaluate risk factors. 14 Q. That's not what Dr. Neel 15 told us the other day. So we'll have to 16 see whether he's right or you're right. 17 A. Can you show me that 18 statement? I believe he was talking 19 about that there's issues about different 20 subtypes of ovarian cancer. I didn't see 21 that -- and that -- I don't think he said 22 that -- 23 Q. He was very clear that risk 24 factors are different between the two.</p>	<p style="text-align: right;">Page 265</p> <p>1 THE WITNESS: I cannot say 2 that with certainty. 3 I -- you know, it's 4 definitely not in the title, but I 5 can't say for sure if -- if there 6 was talc somewhere mentioned in 7 all 200 publications. I don't 8 know with certainty. 9 BY MR. TISI: 10 Q. Any publications about 11 asbestos? 12 A. No. 13 Q. Any publications about 14 asbestos and ovarian cancer? 15 A. Again, there are no 16 publications in ovarian cancer. So no. 17 Q. Any publications where you 18 reviewed evidence regarding causation for 19 any disease through a Bradford Hill 20 guideline? 21 A. So that is a little harder 22 to -- to -- I'll have to go through and 23 look through all the things. I mean, 24 I -- I don't know for certain whether or</p>

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<p style="text-align: right;">Page 266</p> <p>1 not I discuss -- any of the publications 2 discuss causation. 3 I know I have publications 4 that establish associations with things. 5 And we just don't go any further, because 6 association is not causation and there 7 was no reason to establish whether it was 8 causal or not. 9 Q. Right. So my question is, 10 have you ever done an article where you 11 did what you did here, which is look at 12 all the evidence, try to synthesize it 13 and determine whether or not there's 14 cause and effect that you can think of? 15 MS. MILLER: Objection. 16 THE WITNESS: So I would 17 have to say that I believe there 18 are articles here that we have 19 established association and we 20 realize that it -- it didn't merit 21 going through Bradford Hill 22 because it was -- because of the 23 methodology we did, that, you 24 know, we weren't -- we didn't</p>	<p style="text-align: right;">Page 268</p> <p>1 in publication, in some of my 2 publications, as I used in this analysis. 3 Q. Do you think that if I went 4 through each and every article there 5 would be any mention of Bradford Hill? 6 A. I'm not sure with 7 100 percent certainty. But that may well 8 be the case. Just again, because it 9 doesn't say Bradford Hill does not mean 10 that the underlying methodology that was 11 used was not based on the Bradford Hill 12 framework. 13 Q. Isn't it true that your 14 contribution to the vast majority of your 15 200-plus articles is statistical design 16 and statistical evaluation and to the 17 statistical methods you used in the paper 18 and that you are not either the first 19 author or the last author? 20 MS. MILLER: Objection. 21 That's like very, very, very 22 compound. 23 THE WITNESS: I don't quite 24 understand the question. I mean,</p>
<p style="text-align: right;">Page 267</p> <p>1 think there -- it was sufficient 2 to, like perhaps the odds -- the 3 risk ratio was like 1.3 or 4 something, pretty small. 5 BY MR. TISI: 6 Q. Okay. And so the answer to 7 my question is, because of the results 8 that you got in your studies, you have 9 never done in your published literature a 10 full-blown Bradford Hill causation 11 analysis because you didn't get that far? 12 MS. MILLER: Objection. 13 That mischaracterizes the 14 testimony. 15 BY MR. TISI: 16 Q. If it is, correct me, 17 please. 18 A. No. In order to establish 19 causation, you have to start with that. 20 And if it doesn't show that there's 21 causation, why would you write in sort of 22 a whole article, you know, we did 23 Bradford Hill criteria? I mean, I'm 24 saying that the same methodology is used</p>	<p style="text-align: right;">Page 269</p> <p>1 I can point out to numerous 2 publications, like, for clinical 3 trials. Typically, the first 4 author is the chair of the 5 clinical trial. The second author 6 is the -- the statistician that is 7 on the clinical trial, to 8 recognize their role in the design 9 of the study, as well as the 10 interpretation of the data. 11 BY MR. TISI: 12 Q. My question is -- 13 MS. MILLER: She's answering 14 your question. 15 MR. TISI: You're not 16 answering my question, Doctor, 17 honestly. 18 MS. MILLER: She's doing her 19 best. 20 MR. TISI: She's not. 21 BY MR. TISI: 22 Q. I said in, how many -- very 23 few of these articles -- in fact, I think 24 I counted eight. I have to go back and</p>

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<p>1 check, it's certainly under ten, where 2 you were either the first or last author. 3 Would that be about accurate? 4 MS. MILLER: Objection. 5 THE WITNESS: Yeah, I -- I 6 don't know. I mean, if you say 7 you counted it, I can go through 8 and count. But I'm just not sure. 9 I'm trying to answer sort of what 10 my role is in these studies. 11 BY MR. TISI: 12 Q. It would -- 13 A. And again, you don't know 14 this field, but in clinical trials, I 15 would never be the first and last author 16 because I am not the study chair. 17 The role -- what shows the 18 contribution of me is the second 19 position, and there are many where I am 20 the second position. And in fact, on 21 things that have changed practice. 22 Q. You have criticized 23 Dr. Smith-Bindman and her meta-analysis, 24 correct?</p>	<p>1 meta-analyses that I can count. She has 2 six published in JAMA. JAMA is a high 3 impact journal, would you agree? 4 A. Yes, JAMA is a high impact 5 journal. 6 Q. Right. She has two 7 meta-analyses in high impact journals. 8 Can you tell me whether or not you've 9 ever published a meta-analysis in any 10 high impact journal? 11 A. Can you show me those 12 references to the meta-analyses that she 13 published? 14 Q. 47 -- 47 -- she or you? 15 A. Not me. Hers. 16 Q. I'm asking about yours. 17 MS. MILLER: But you asked 18 about -- 19 THE WITNESS: No, you asked 20 about her. 21 MS. MILLER: You said she 22 has six published in JAMA. Would 23 you agree? 24 MR. TISI: No, I said two.</p>
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<p>1 A. I -- I show where I think 2 there are some limitations in her 3 analyses, yes. 4 Q. Well, you said that they 5 were flawed. I think that's -- you used 6 the word flawed. 7 A. I may have used the word 8 "flawed." 9 Q. Do you know that 10 Dr. Smith-Bindman, unlike yourself, is 11 actually submitting her analysis to peer 12 review. Does that surprise you? 13 A. I did not know that. 14 MS. MILLER: When you're 15 ready, they sometimes take away 16 the food away by 1:00. So we 17 should probably wrap up and take a 18 break. 19 MR. TISI: I'm almost done 20 with this section here. 21 MS. MILLER: Okay. 22 BY MR. TISI: 23 Q. So you've published. You've 24 been on articles where -- three</p>	<p>1 BY MR. TISI: 2 Q. No, I didn't ask -- I said I 3 will represent to you that she has two 4 published in JAMA. She has six 5 meta-analyses published total. 6 MS. MILLER: I'm looking at 7 the realtime. It says, "You have 8 published -- you've been on 9 articles or three meta-analyses 10 that I can count. She has six 11 published in JAMA. JAMA is a high 12 impact journal. Would you agree?" 13 BY MR. TISI: 14 Q. Okay. Well, let me rephrase 15 the question. She has six meta-analyses, 16 two published in JAMA. You would agree 17 that JAMA is a high impact journal? 18 A. Well, I just want to see -- 19 I want to see those citations -- 20 Q. I'm not asking you -- 21 A. -- because you're saying 22 she. I mean, does it -- where is she in 23 the author list. I don't know even what 24 you're --</p>

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<p>1 Q. Is that important?</p> <p>2 A. I don't know. I just want</p> <p>3 to see what the titles are of the --</p> <p>4 Q. Then let's talk about you.</p> <p>5 A. -- articles.</p> <p>6 Q. Let's talk about you. In</p> <p>7 your three published meta-analyses,</p> <p>8 Number 47, 68, and 142 on your CV, were</p> <p>9 you the lead designer of the study?</p> <p>10 A. I was --</p> <p>11 MS. MILLER: Do you want to</p> <p>12 see?</p> <p>13 BY MR. TISI:</p> <p>14 Q. 47, 68, and 142.</p> <p>15 A. Thank you. Yeah, yeah,</p> <p>16 yeah.</p> <p>17 MS. MILLER: Would it be on</p> <p>18 this list? I found the 47.</p> <p>19 THE WITNESS: No, it's not</p> <p>20 that list.</p> <p>21 MS. MILLER: There's so many</p> <p>22 lists.</p> <p>23 THE WITNESS: It would be my</p> <p>24 CV maybe? Is that what you're</p>	<p>1 MR. TISI: I understand.</p> <p>2 I'm almost done. The food is</p> <p>3 not --</p> <p>4 MS. MILLER: I think we've</p> <p>5 just been going an hour. It's a</p> <p>6 good time to break.</p> <p>7 MR. TISI: I understand.</p> <p>8 I'm just at the end of the --</p> <p>9 MS. MILLER: Okay. Great.</p> <p>10 MS. SHARKO: Did you miss</p> <p>11 me?</p> <p>12 BY MR. TISI:</p> <p>13 Q. The next one is which one,</p> <p>14 68?</p> <p>15 A. And I see that one.</p> <p>16 Q. And that's -- which one is</p> <p>17 that one? Is that O'Sullivan, or is that</p> <p>18 142?</p> <p>19 A. No, 68 is Witt, Gami,</p> <p>20 Ballman, Brown.</p> <p>21 Q. And the other one is -- 142</p> <p>22 is O'Sullivan.</p> <p>23 A. Yes.</p> <p>24 (Document marked for</p>
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<p>1 talking about my CV?</p> <p>2 MR. TISI: Let me see it.</p> <p>3 MS. MILLER: Is this the</p> <p>4 document? It's 47, Witt, Ballman.</p> <p>5 THE WITNESS: That's one.</p> <p>6 MS. MILLER: So then I think</p> <p>7 this is maybe the right list.</p> <p>8 THE WITNESS: Yeah, I see</p> <p>9 it.</p> <p>10 MS. MILLER: Okay. Great.</p> <p>11 THE WITNESS: Again, you see</p> <p>12 I'm second. So that means I</p> <p>13 played a very integral role in</p> <p>14 this --</p> <p>15 BY MR. TISI:</p> <p>16 Q. That's Number 47?</p> <p>17 A. Yep.</p> <p>18 Q. And what's that one called?</p> <p>19 A. "The Incidence of Stroke</p> <p>20 After Myocardial Infarction: A</p> <p>21 Meta-Analysis."</p> <p>22 MS. MILLER: Again, I just</p> <p>23 want to suggest that we break for</p> <p>24 lunch soon because --</p>	<p>1 identification as Exhibit</p> <p>2 Ballman-17.)</p> <p>3 BY MR. TISI:</p> <p>4 Q. I'm going to hand you</p> <p>5 O'Sullivan. Did you play a substantial</p> <p>6 role in the meta-analysis which is 142,</p> <p>7 the O'Sullivan meta-analysis?</p> <p>8 A. What do you mean by a</p> <p>9 substantial role?</p> <p>10 Q. Did you design it?</p> <p>11 A. I was part of the group, so</p> <p>12 this is actually a pooled analyses.</p> <p>13 Q. It says meta-analysis in the</p> <p>14 title.</p> <p>15 A. Yeah. So you can't get</p> <p>16 everything out of titles, right? So a</p> <p>17 pooled analysis is a type of</p> <p>18 meta-analysis. It's a much stronger</p> <p>19 meta-analysis in the sense that what</p> <p>20 happens is you get individual patient</p> <p>21 level data.</p> <p>22 So this is pooling data</p> <p>23 from, like, the largest clinical trials</p> <p>24 that were done in adjuvant trastuzumab,</p>

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<p>1 and that's Herceptin for women that have 2 HER2 positive breast cancer. I control 3 the data for one of the big trials in 4 trastuzumab. 5 And so I was part of this 6 group that just came together and said, 7 wow, we should use all this data, pool it 8 together to address a rare type of 9 situation, which was done here. 10 Q. Did you do any of the 11 writing of this? 12 A. I -- I did not do the first 13 draft, but I did go through and make 14 revisions and comments. 15 Q. Isn't it true that you were 16 identified as primarily the collection 17 and assembly of data? 18 A. That was probably the 19 biggest role that I played in this study. 20 But I did -- yeah. 21 Q. Isn't that kind of what 22 you -- isn't that kind of what you've 23 done in the meta-analysis that you've 24 done, you're primarily the collection of</p>	<p>1 times. 2 BY MR. TISI: 3 Q. I'm asking you -- I'm asking 4 you whether or not you, by training and 5 experience, you think you have better 6 qualifications than Dr. Smith-Bindman? 7 A. I can't answer that. I 8 mean, I don't know. I mean, I would have 9 to go through and look at all -- at all 10 the stuff she's done. My only exposure 11 to her was the study that she's done, and 12 I don't think it was done particularly 13 well. 14 Q. The one she's submitting for 15 peer review? 16 A. Has she submitted it? Has 17 it been published? I wonder if it will 18 be published actually. 19 Q. Well, we'll have to see how 20 that goes. 21 MR. TISI: I am -- this is 22 a -- this is a good time for 23 lunch. 24 THE VIDEOGRAPHER: The time</p>
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<p>1 data? 2 A. No, that's not true. 3 Q. Okay. So the other two 4 would be ones that you did more than 5 that, 47 and 58? 6 A. Well, you know -- 7 Q. 47 and 68. Excuse me. 8 A. Yes, I mean I -- I -- I -- 9 it's sort of -- it's a whole 10 collaborative thing. It's not like, you 11 know, this is a service that you're 12 trying to imply. It's a scientific 13 endeavor that's done as a collaborative 14 experience among various different 15 scientists with different expertise. 16 Q. Do you think you're as -- 17 just have one -- do you think you have 18 the same qualifications or better than 19 Dr. Smith-Bindman in doing a 20 meta-analysis? 21 MS. MILLER: Objection. I 22 think she testified that she 23 wasn't testifying about other 24 witnesses' qualifications three</p>	<p>1 is 12:49 p.m. Off the record. 2 - - - 3 (Lunch break.) 4 - - - 5 AFTERNOON SESSION 6 - - - 7 THE VIDEOGRAPHER: We are 8 back on the record. The time is 9 1:27 p.m. 10 - - - 11 EXAMINATION (Cont'd.) 12 - - - 13 BY MR. TISI: 14 Q. Doctor, before lunch -- I 15 want to finish up talking about your 16 qualifications. I want to move onto a 17 new topic here. 18 I want to ask you about two 19 questions, two or three questions I think 20 about Bradford Hill, and then we're going 21 to move on to your analysis. 22 A. Okay. 23 Q. Okay. Just so we know, 24 we'll talk about case -- case-control and</p>

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<p style="text-align: right;">Page 282</p> <p>1 cohort studies, just to kind of give you 2 a little bit of roadmap of where I'm 3 going. All right? 4 Bradford Hill, we can both 5 agree, we've used the word criteria, but 6 we both agree that these are -- this 7 is -- these are guidelines, correct? 8 A. I call it a framework. 9 Q. Okay. And just to be clear, 10 you use the word criteria. And I've 11 actually used it in my -- in my 12 questions. 13 When you use the word 14 criteria, we really are talking about, 15 these are different considerations that 16 should be looked at when you're looking 17 at the question of causation generally. 18 A. Yeah. So Bradford Hill has 19 nine different considerations that one 20 should consider with -- within the 21 framework of doing a Bradford Hill 22 analysis. 23 Q. Right. And just -- just to 24 be clear for the record, this isn't like</p>	<p style="text-align: right;">Page 284</p> <p>1 being used. 2 BY MR. TISI: 3 Q. And that's a -- that's a 4 methodologic flaw that you identified 5 that you think the plaintiffs' experts 6 didn't adequately consider the -- that -- 7 that cohort studies are higher on the 8 evidentiary ladder than case-control 9 studies, true? 10 A. I -- I believe that some of 11 plaintiffs' experts just sort of, just 12 flat out say that case-controlled studies 13 have the higher evidence than the cohort 14 studies. 15 Q. Let's talk about that for a 16 moment. On Page 3, on your -- your -- 17 excuse me. On your conclusion, we -- it 18 talks about the levels of evidence. Do 19 you remember, you -- we -- we talked 20 about that, that's Exhibit Number 2. You 21 actually mention it in your conclusion, 22 right? 23 A. So I'm sorry, where -- 24 where --</p>
<p style="text-align: right;">Page 283</p> <p>1 a cookbook or a mathematical formula. 2 Bradford Hill is -- is a balancing of the 3 evidence using that -- that framework as 4 a guideline? 5 MS. MILLER: Objection. 6 THE WITNESS: So I mean, 7 research is not a cookbook. But, 8 you know, one can apply Bradford 9 Hill -- I mean I think there's 10 incorrect ways of applying 11 Bradford Hill. 12 BY MR. TISI: 13 Q. Okay. And one of them, 14 you -- you -- and this leads into my next 15 question is, you believe that there are 16 levels of evidence that trump other 17 levels of evidence, generally speaking? 18 MS. MILLER: Objection. 19 THE WITNESS: In the 20 epidemiology literature, it's 21 pretty much I think agreed upon 22 that there are -- there are 23 different levels of evidence based 24 upon what type of study design is</p>	<p style="text-align: right;">Page 285</p> <p>1 Q. It's the second sentence, it 2 says, "In assessing studies for the level 3 of evidence in the data." 4 A. Okay. 5 Q. And we agreed -- 6 A. Yeah. So I used that word. 7 Yeah, I used that word. 8 Q. And we agreed before that 9 the level of evidence you were talking 10 about was prospective case-controlled -- 11 prospective cohort studies versus case 12 controls? 13 A. No, no, no. That's not 14 correct here. 15 Q. Okay. 16 A. This here, as I'm looking at 17 the evidence in totality across 18 everything I looked at. 19 Q. Okay. But below in the -- 20 on Page 53 you say, "Cohort studies 21 provide stronger evidence than do 22 case-control studies." 23 It's near the -- like five 24 lines --</p>

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<p>1 A. "Cohort studies provide 2 stronger evidence do" -- "than do 3 case-control studies." 4 That's stated there, yes. 5 Q. Okay. And you think that's 6 a general epidemiologic principle, 7 correct? 8 A. I do. 9 Q. And you repeat that 10 repeatedly throughout your report, 11 correct? 12 A. I -- I may state it several 13 times. 14 Q. Okay. Let's -- let's look 15 at them. 16 First of all, if you go to 17 Page 4 of your report, you talk about the 18 levels of evidence with increasing 19 reliability. It says, on -- "Figure 1 20 illustrates the level of evidence with 21 each trial design with increasing 22 evidence moving up the pyramid." 23 Do you see that? 24 A. I do see that.</p>	<p>1 Q. And under that are 2 case-control studies? 3 A. Yes. 4 Q. And under that are case 5 reports and case series? 6 A. Yes. 7 Q. Okay. And you have kind of 8 bright lines between the two, to really 9 differentiate for the reader, that there 10 is -- these are established principles, 11 correct -- 12 MS. MILLER: Objection. 13 BY MR. TISI: 14 Q. -- that -- that cohort 15 studies are -- are better than 16 case-control studies, are better than 17 case reports and case series, et cetera? 18 MS. MILLER: Objection. 19 THE WITNESS: I -- I don't 20 think I said better. And I think 21 the lines are there just -- just 22 so there has -- there doesn't have 23 to be lines there. 24 And what it's trying to show</p>
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<p>1 Q. And then you have a pyramid? 2 A. I do. 3 Q. Okay. And what is the 4 purpose of this illustration that you 5 included in your report on Page 4? 6 A. Just -- just to -- to give a 7 visual for how the different study 8 designs compared to each other in terms 9 of -- of the level of evidence that 10 epidemiologists believe are -- are 11 conveyed in each of the different types 12 of studies. 13 Q. And below randomized 14 controlled trial -- there's randomized 15 and there's meta-analysis, and by that 16 you mean meta-analysis of controlled 17 trials, correct? 18 A. Yes. 19 Q. Okay. And then underneath 20 are RCTs? 21 A. Mm-hmm. 22 Q. Okay. And under that are 23 cohort studies? 24 A. Yes.</p>	<p>1 is the level of evidence contained 2 in those. I don't -- I mean, I 3 don't know what you mean by 4 better. 5 BY MR. TISI: 6 Q. Well, okay. Cohort studies, 7 according to your chart, are more 8 reliable than case-controlled studies? 9 A. Again, they -- they have a 10 higher level of evidence. I don't -- I 11 don't know if I would say reliable is the 12 same as level of evidence. 13 Q. Okay. Now, you don't have 14 any citation for this, for this chart, do 15 you? 16 Did you create this or is 17 this from some other place? 18 A. I -- I have seen this in 19 numerous, numerous different places, but 20 I made this particular figure by myself. 21 Q. Okay. So there's no 22 citation for this? 23 A. Not in this document, but 24 there is in the epidemiology literature.</p>

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<p>1 Q. Okay. Well, there's no 2 citation for this, correct? 3 MS. MILLER: Objection. 4 Asked and answered. 5 BY MR. TISI: 6 Q. Because what I'm going to 7 ask -- I'm going to ask you questions 8 about that, but you did not provide a 9 citation for Figure 1 -- 10 MS. MILLER: Objection. 11 BY MR. TISI: 12 Q. -- where you got that 13 statement from? 14 MS. MILLER: I'm sorry, I 15 just always think you're done with 16 your question so I object, and 17 then you keep going. That's now 18 three questions and it's one 19 question. We're having the same 20 ongoing issue that we had before. 21 Objection to all three parts 22 of that question. 23 BY MR. TISI: 24 Q. Okay. Doctor --</p>	<p>1 you know, how the P-values were -- 2 were calculated because it's -- 3 it's sort of a given -- 4 BY MR. TISI: 5 Q. Okay. 6 A. -- knowledge. 7 Q. On Page 7 of your report. 8 And I'm just going to read a couple 9 places where you make this point. 10 On Page 7, 3.3, you say, 11 "Generally in my experience, prospective 12 cohort studies yield a higher level of 13 evidence than case-control studies." 14 That's the first sentence 15 in -- 16 A. That is what it says there. 17 Q. Okay. Could you just put a 18 line next to that so we can -- we may 19 come back to that. Could you just put 20 a -- 21 A. May I write? 22 Q. Yeah, you can write on that. 23 MS. MILLER: I think she 24 can --</p>
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<p>1 MS. MILLER: So which 2 question is -- 3 BY MR. TISI: 4 Q. Doctor, do you have a 5 citation to this chart? 6 A. I made the chart up myself. 7 And -- and it is just an underlying 8 epidemiological principle, so it -- it 9 doesn't have a citation. It would be 10 like cite -- citing what a T test is. 11 Q. Okay.4? 12 A. It's sort known through the 13 literature as to this is... 14 Q. Okay. So your -- so your -- 15 your view if it's a general principle, 16 you don't have to cite something to 17 support it? 18 MS. MILLER: Objection. 19 THE WITNESS: You know, 20 again, it's -- it's a general 21 principle and, you know, and when 22 one is talking about odds ratios 23 or P-values and things like that, 24 we, you know, we're not citing,</p>	<p>1 BY MR. TISI: 2 Q. Yeah, would you, please? 3 Yes, it's an exhibit. Thank you. 4 MS. MILLER: Why don't we 5 just use a sticky? 6 MR. TISI: No, because I'm 7 going to -- I want a record of 8 what we did. 9 BY MR. TISI: 10 Q. So on page -- and there's no 11 citation -- 12 MS. MILLER: She is not 13 creating an exhibit here. 14 MR. TISI: Yeah, she is. 15 MS. MILLER: No. 16 MR. TISI: Yeah, she is. 17 MS. MILLER: Well, I am 18 objecting to that. 19 MR. TISI: You can object to 20 it. 21 MS. MILLER: If you want 22 stickies she can put stickies. 23 MR. TISI: You can object to 24 it. You can object to it, and</p>

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<p>1 we'll ask the -- we can take a 2 break and call the judge if you 3 want to do that. 4 MS. MILLER: Any time you 5 want. You seem to be threatening 6 that a lot. 7 MR. TISI: Do you want to do 8 that? 9 MS. MILLER: It's up to you. 10 MR. TISI: Do you want to do 11 that? Because I'm happy to -- 12 because I would like to draw on 13 that exhibit there where she -- 14 MS. MILLER: Well, she's 15 already drawn it. I will see what 16 else you ask of her. 17 BY MR. TISI: 18 Q. On Page 17, second full 19 paragraph. 20 A. Yes. 21 Q. Does it say -- does it say, 22 "When the results across study designs 23 are not consistent, i.e., case-control 24 study reports a statistically significant</p>	<p>1 going off of Figure 1, which is a 2 generally accepted principle in 3 epidemiology. 4 Q. Okay. But the answer there 5 is there's no citation there, right? 6 MS. MILLER: Objection. 7 THE WITNESS: There's no 8 citations for many things that are 9 general sort of principles of 10 epidemiology or other facts. 11 BY MR. TISI: 12 Q. Please go to Page 26, 13 please. 14 A. There's no citation there. 15 I take it back. But I do have citations 16 in -- and if you give me a minute to 17 look, I can -- 18 Q. No, I want to see -- 19 A. -- find citations where 20 there's a higher level of evidence -- 21 Q. I'm going through every 22 place where you've said it. And I want 23 to put this, Doctor. First, follow me. 24 MS. MILLER: Chris, excuse</p>
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<p>1 association, but cohort studies do not, 2 the study with the accepted higher level 3 of evidence is the cohort study because 4 it eliminates bias such as recall bias"? 5 A. That's what it states. 6 Q. Okay. Can you put a little 7 star next to that, please? 8 MS. MILLER: A star. 9 BY MR. TISI: 10 Q. Or a whatever. So -- I want 11 to be able to come back to it. Could you 12 do that, ma'am? 13 A. I'll remember where it is. 14 Q. No, could you just put a -- 15 please, would you do what I've asked, 16 please? 17 MS. MILLER: I have a 18 standing objection to this. I 19 think this is improper. 20 MR. TISI: You can object. 21 BY MR. TISI: 22 Q. On Page 26 -- and of course 23 you do not have a cite to that? 24 A. As I mentioned, this is</p>	<p>1 me. 2 MR. TISI: I ask -- I'm 3 asking the questions. 4 BY MR. TISI: 5 Q. Is there a citation after 6 that statement? The answer is no. 7 The next one, on Page 26, do 8 you see that it says, "It is well 9 established as discussed above that there 10 are more potential or confounding 11 case-control studies compared to 12 prospective cohort studies since the 13 prospective cohort studies are not prone 14 to participant selection, recall bias 15 with respect to exposure, which is why 16 they're considered to yield stronger 17 level of evidence than case-control 18 studies." 19 Do you see that? 20 A. On Page 26? No, I -- 21 Q. Second sentence of the first 22 full paragraph. "It is well 23 established" -- 24 A. Which it says, "As discussed</p>

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<p>1 above." So I'm going to go and look at 2 the "as discussed above" for the 3 citations. 4 So I have a citation to a 5 book called case-control studies. And 6 actually my references are transposed 7 there. 8 That discusses sort of the 9 level of evidence. 10 Q. Okay. So you think that's 11 the citation. What is the name of that? 12 What is the name of that one? 13 A. So it's listed as six. But 14 it should be seven there, "Case-Control 15 Studies: Design, Conduct and Analyses." 16 Q. Okay. I'll look that up. 17 Let's go to page -- 18 A. And also -- I also think I 19 have more. Oh, it's in the meta-analyses 20 that we were talking about. And so 21 there's a Citation 23. And I say, "So 22 this is because, due to the effects of 23 confounding and bias, observational 24 studies may produce estimates that</p>	<p>1 A. "Cohort studies yield a 2 higher level of evidence. Hill observed, 3 'I would put myself at a good deal of 4 weight upon similar results reached in 5 quite different ways, i.e., prospectively 6 and retrospectively." 7 Q. But they're not -- you can 8 have prospective case-control studies and 9 you can have retrospective case-control 10 studies. You could have prospective -- 11 A. How can you have prospective 12 case-control studies? 13 Q. Actually, you're right. You 14 can have prospective and retrospective 15 cohort studies, correct? 16 A. It depends upon how you 17 define it. 18 Q. He didn't talk about 19 case-controls and cohorts, did he? 20 A. I don't know. I'll have to 21 look up Bradford Hill. 22 Q. Okay. But you do say, 23 without citation, "Cohort studies yield a 24 higher level of evidence," correct, on</p>
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<p>1 deviate from a true causal." 2 That's -- that's 3 observational studies in general. 4 Q. But nothing saying that it's 5 a higher level of evidence? I'm looking 6 for a citation that says cohort studies 7 are a higher level of evidence as a 8 general rule than case-control studies. 9 A. So again, I think -- it is 10 implied throughout. 11 Q. It's implied, but it's not 12 cited. And I'm looking for a citation to 13 that. It's not only implied. Actually, 14 you come right out and say it several 15 times. 16 A. Yes. 17 Q. Okay. So let's go to Page 18 28, last paragraph, last sentence. 19 A. Yes. 20 Q. It says, "Cohort studies 21 yield a higher level of evidence." No 22 citation for that either? 23 A. I'm sorry. Last sentence? 24 Q. Cohort studies. Page 28.</p>	<p>1 Page 28? 2 A. There's no explicit citation 3 on -- for the sentence that you read. 4 Q. Let's go to Page 35. Third 5 paragraph, last sentence. "Now, the 6 cohort studies observed a dose-response 7 relationship. Cohort studies provide a 8 higher level of evidence than do 9 case-control studies." 10 (Brief teleconference 11 interruption.) 12 THE WITNESS: Yes, there's 13 no citation after that particular 14 sentence, I agree. 15 BY MR. TISI: 16 Q. Okay. So in this one 17 there's no citation to cohort studies 18 providing a higher level of evidence than 19 do case-control studies, true? 20 A. There's no citation after 21 that particular sentence. You are 22 correct. 23 Q. Okay. And you have a 24 statement in the conclusion that cohorts</p>

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<p>1 are better than case-control, and that 2 also doesn't have a citation, correct? 3 A. What conclusion? 4 Q. On the conclusion on Page 5 53. 6 A. I do not have a citation 7 after that sentence. 8 Q. Now, on Page 45, in your 9 criticism of Dr. Smith-Bindman, you say, 10 in the middle of the page, "As I said 11 above there is evidence in the literature 12 that cohort studies provide less biased 13 information than case-control studies, 14 and I have not found instance where 15 the -- instances where the opposite is 16 argued." 17 Do you see that? 18 A. Mm-hmm. 19 Q. Okay. And there's no 20 citation to that as well, right? 21 A. Well, if I didn't find any 22 instances where that has been showing, 23 there wouldn't be citations. 24 Q. Did you look?</p>	<p>1 conclusion, rely very heavily on the 2 concept that, as a general rule, cohort 3 studies are better than case -- 4 case-control studies; is that true? 5 MS. MILLER: Objection. 6 THE WITNESS: It's not a 7 concept. It is a generally 8 accepted and well accepted 9 principle of epidemiology that 10 there is more evidence in cohort 11 studies than there is in 12 case-control studies because they 13 eliminate confounding. 14 And I'm just -- I need to 15 look, and I'm sure there are some 16 citations here. 17 BY MR. TISI: 18 Q. Well, the only cite you 19 mention are -- are -- it's Number 7 in 20 your report, the case-control studies -- 21 A. Right, but buried within 22 some of these other studies there are 23 statements such as, you know, it was 24 thought that oral contraceptives, you</p>
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<p>1 A. I did. 2 Q. You did? 3 A. Yeah. I have not seen a 4 study that has said there is a higher 5 level of evidence in case-control studies 6 than there is in cohort studies as a 7 whole. 8 Q. Actually, I didn't -- 9 actually, I didn't say higher level. I 10 said that cohort studies are as a whole 11 better than case-control studies. 12 A. No. Can -- what -- was that 13 the question? 14 Q. The statement is, "I have 15 not found the opposite to be true." 16 A. Exactly. And I don't have a 17 citation for "I have not found the 18 opposite to be true," because -- because 19 there is no literature that says the 20 opposite is true. 21 Q. Okay. The truth is that 22 your methodology, your opinions -- and 23 we've gone through several places in your 24 report -- rely very heavily on, and your</p>	<p>1 know, cause breast cancer based on 2 case-control studies, but then when 3 cohort studies were done, the opposite 4 was found due to the fact that they are a 5 lower level of evidence and biases and 6 confounding -- 7 Q. Are there other -- 8 A. -- in case-control studies. 9 Q. I apologize. 10 Are there other instances 11 where case-control studies have found the 12 real cause that cohorts haven't? 13 A. I don't know off of the top 14 of my head. 15 Q. But you know full well that 16 the current view in epidemiology is that 17 evidentiary period does not provide a 18 bright line between -- between 19 case-control and cohorts, don't you? 20 MS. MILLER: Objection. 21 THE WITNESS: Can you show 22 me where -- where getting you're 23 that information and why I should 24 know full well?</p>

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<p>1 BY MR. TISI: 2 Q. Let's start with your own 3 statement in the Viagra litigation. 4 Okay. 5 Let's -- let me show you 6 what I have marked as Exhibit Number 21. 7 (Document marked for 8 identification as Exhibit 9 Ballman-18.) 10 BY MR. TISI: 11 Q. Do you remember -- do you 12 remember -- 13 MR. SOILEAU: This is not 14 going to be 21 in this deposition. 15 MR. TISI: I'm sorry. For 16 the record, this is 18. 17 BY MR. TISI: 18 Q. And you have a -- do you 19 recall having a section in your Viagra 20 report which talks about levels of 21 evidence? 22 A. Not off of the top of my 23 head. I need to see it. 24 MS. MILLER: Is this the</p>	<p>1 for the record what you wrote in Viagra? 2 A. Yeah, this is -- this is 3 very abbreviated. Because I see I have a 4 section on randomized clinical trials 5 right here -- 6 Q. I'm asking you what you 7 read -- can you read -- can you read what 8 you wrote in Viagra? 9 MS. MILLER: Objection. 10 THE WITNESS: Read what? 11 BY MR. TISI: 12 Q. Read where it says levels of 13 evidence. Section B. There's a full 14 paragraph under levels of evidence. 15 Could you read what it says? 16 A. Sure. "Cancer epidemiology 17 attempts to identify risk factors that 18 are causative agents of cancer. Knowing 19 what causes a cancer may lead to 20 therapies that benefit patients and/or 21 strategies to minimize the exposure to a 22 risk. There are different levels of 23 evidence for determining whether a factor 24 is causal based on the underlying study</p>
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<p>1 whole report or just a portion of 2 the report? 3 MR. TISI: It's a portion of 4 the report. 5 MS. MILLER: Yeah, I don't 6 think that's right. I think that 7 you need to give her the whole 8 report. 9 MR. TISI: You can object -- 10 you know, you haven't even looked 11 at it. 12 MS. MILLER: Would you like 13 a whole report? 14 THE WITNESS: I would like 15 the whole report. 16 MR. TISI: Okay. Let me -- 17 you may like it. You can use your 18 time to do that. 19 BY MR. TISI: 20 Q. Doctor, I'm -- there's a 21 section in here, full paragraph on levels 22 of evidence. Do you see that? 23 A. Yes. There is a -- yes. 24 Q. Okay. Would you please read</p>	<p>1 design. A recognized ranking of common 2 study designs from the greatest level of 3 evidence to lowest is, one, randomized 4 clinical trials, two, cohort and 5 case-control studies, and three, case 6 reports and case series." 7 Then I go on and -- 8 Q. And just -- just -- 9 A. -- I list Number 1 -- 10 Q. I just asked you -- I simply 11 just -- 12 A. I -- I'm not finished. 13 Please, can you let me finish. Please. 14 Q. No. I asked you to read in 15 the record. Your lawyer if they want to 16 can do that. Okay? And I'm going to -- 17 MS. SHARKO: No, she has the 18 right to finish her answer, 19 Mr. Tisi, and you know that -- 20 MR. TISI: Who is -- who 21 is -- she has a right -- I asked 22 her to read the paragraph. 23 MS. SHARKO: You know that. 24 MR. TISI: That is -- to my</p>

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<p>1 knowledge --</p> <p>2 MS. SHARKO: What kind of</p> <p>3 question is that? A reading test?</p> <p>4 MR. TISI: I asked -- yes.</p> <p>5 That's what I asked her to do, and</p> <p>6 she read it. Thank you.</p> <p>7 THE WITNESS: But this</p> <p>8 misrepresents what this --</p> <p>9 MS. SHARKO: No, but she has</p> <p>10 the right --</p> <p>11 THE WITNESS: -- this</p> <p>12 paragraph is saying, because it's</p> <p>13 incomplete and taken out of</p> <p>14 context.</p> <p>15 BY MR. TISI:</p> <p>16 Q. I'm going to --</p> <p>17 A. And I see that you've</p> <p>18 provided -- it says Number 1, randomized</p> <p>19 clinical trials, and then -- and then it</p> <p>20 goes over on the next page. And then it</p> <p>21 stops because I'm sure I have a section</p> <p>22 on -- on case-control studies and a</p> <p>23 section on cohort studies, and it's</p> <p>24 consistent with what I say here.</p>	<p>1 Have you looked in textbooks to see</p> <p>2 whether that is true?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. I'm going to show you</p> <p>5 Dr. Rothman's textbook -- textbook on --</p> <p>6 on epidemiology.</p> <p>7 A. The whole textbook?</p> <p>8 Q. I'm showing you the entire</p> <p>9 chapter. The entire chapter.</p> <p>10 A. And the table of contents?</p> <p>11 MR. TISI: I can give --</p> <p>12 actually, I can give you the whole</p> <p>13 book. Let's do this.</p> <p>14 BY MR. TISI:</p> <p>15 Q. And if you feel like you</p> <p>16 need to look at the book, I'm happy to do</p> <p>17 it.</p> <p>18 MS. MILLER: I don't think</p> <p>19 there's any reason to take that</p> <p>20 tone with the witness --</p> <p>21 MR. TISI: I mean, you know,</p> <p>22 honestly --</p> <p>23 MS. MILLER: We've been very</p> <p>24 polite in these depositions. This</p>
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<p>1 Q. But you lump them --</p> <p>2 A. They are lumped together --</p> <p>3 Q. But you -- Doctor, this</p> <p>4 isn't -- this really isn't an argument.</p> <p>5 I'm asking you whether for the purposes</p> <p>6 of your Viagra case, where you describe</p> <p>7 the level of evidence, instead of five</p> <p>8 levels, you describe three.</p> <p>9 A. I think that is a</p> <p>10 mischaracterization --</p> <p>11 Q. Okay.</p> <p>12 A. -- because this is not</p> <p>13 complete.</p> <p>14 Q. All right.</p> <p>15 A. That they are put together</p> <p>16 because they are both observational</p> <p>17 studies, and then I'm sure I have a</p> <p>18 separate section that talks about the</p> <p>19 different aspects of clinical -- of</p> <p>20 case-control studies and cohort studies,</p> <p>21 and say essentially the same thing</p> <p>22 because it's an accepted underlying</p> <p>23 epidemiology principle.</p> <p>24 Q. So let me ask you this.</p>	<p>1 is the first deposition that I'm</p> <p>2 aware where the -- where the</p> <p>3 lawyer has been so rude to the</p> <p>4 witness.</p> <p>5 MR. TISI: I don't think I'm</p> <p>6 being rude at all. I don't think</p> <p>7 I'm being rude at all.</p> <p>8 Okay.</p> <p>9 MS. SHARKO: Maybe not by</p> <p>10 your standards.</p> <p>11 MR. TISI: Certainly not by</p> <p>12 your standards.</p> <p>13 MS. SHARKO: I would</p> <p>14 disagree with that.</p> <p>15 BY MR. TISI:</p> <p>16 Q. Okay. Chapter -- I have the</p> <p>17 book. I'll give you the book.</p> <p>18 For the record, I'm going to</p> <p>19 have this marked as Exhibit Number 19.</p> <p>20 (Document marked for</p> <p>21 identification as Exhibit</p> <p>22 Ballman-19.)</p> <p>23 BY MR. TISI:</p> <p>24 Q. I'm looking at Chapter 8.</p>

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<p>1 And I'm going to give you the exhibit 2 right in front of you. And you can look 3 at the book if you'd like. 4 Doctor? 5 A. Yes, I'm -- I'm -- 6 Q. I have -- I'd like you to 7 look at the exhibit. You can look at the 8 book if you need to -- 9 A. I'm sorry, did -- did you 10 hand it to me? 11 Thank you. 12 Q. Now, this is Chapter 8. 13 It's called "Case-Control Studies." 14 Do you see that? 15 A. It does say case-control 16 studies. 17 Q. And the first 18 paragraph introduces the concept. It 19 says, "In this chapter, we will review 20 case-control designs and contrast their 21 advantages and disadvantages with cohort 22 designs." 23 Do you see that? 24 A. I'm sorry. Which page?</p>	<p>1 the next paragraph. It says, "Cohort 2 studies are not immune from problems 3 often thought to be particular with 4 case-control studies. For example, while 5 a cohort study may gather information on 6 exposure for an entire source population 7 at the outset of the study, it still 8 requires tracing subjects to ascertain 9 exposure variation and outcomes." 10 Do you see that? 11 A. So I'm sorry. I'm trying to 12 take in a lot of information. I'm sorry. 13 I'm going to have to ask you to rephrase. 14 Q. Okay. Does he not say, 15 "Cohort studies are not immune from 16 problems often thought to be particular 17 to case-control studies"? 18 A. That's what that sentence 19 says. 20 Q. Next sentence, he gives an 21 example. "For example, while cohort 22 studies may gather information on 23 exposure for the entire source 24 population, at the outset of the study it</p>
Page 315	Page 317
<p>1 Q. First page. The first 2 paragraph just introduces the topic. 3 A. Yes. 4 Q. Last sentence says, "In this 5 chapter we will review case-control to 6 study designs and contrast their 7 advantages and disadvantages to cohort 8 designs." 9 Do you see that? 10 A. I see that. 11 Q. Okay. The next sentence in 12 the first paragraph. "Conventional 13 wisdom about case-control studies is that 14 they do not yield estimates of effect 15 that are as valid a measure obtained from 16 cohort studies. This thinking may 17 reflect a common misunderstanding in 18 conceptualizing case-control studies 19 which will be clarified later." 20 Do you see that? 21 A. I -- I see that, you read 22 that correctly. 23 Q. Okay. And then he 24 describes, so if you want to go down to</p>	<p>1 still requires tracing of subjects to 2 ascertain exposure variation and 3 outcomes." 4 Do you see that? 5 A. Yes, it does say that. 6 MS. MILLER: Do you want to 7 give her the time to actually read 8 this, instead of plucking out 9 sentences from it? 10 THE WITNESS: Yeah, I 11 mean -- 12 MS. MILLER: You are 13 plucking out one sentence from a 14 paragraph. 15 BY MR. TISI: 16 Q. I'm happy to do -- I'm just 17 asking whether -- where it says -- do you 18 agree with that statement? 19 MS. MILLER: But she has to 20 read the whole thing. 21 THE WITNESS: But I don't 22 know. 23 MR. TISI: No, she doesn't. 24 I'm asking her whether she agrees</p>

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<p style="text-align: right;">Page 318</p> <p>1 with that statement. 2 BY MR. TISI: 3 Q. Do you agree that, "Cohort 4 studies may gather information on 5 exposure for an entire source population 6 at the outset of the study and still 7 requires tracing of subjects to ascertain 8 exposure variations and outcome. If the 9 success of this tracing is related to the 10 exposure and the outcome, the resulting 11 selection bias will behave analogously to 12 the often raised concern of case-control 13 studies." 14 Do you agree with that or 15 disagree with that? 16 MR. LOCKE: Objection. 17 THE WITNESS: I cannot say 18 just off the fly like this because 19 I have to see where they're going 20 with this, if they are just sort 21 of setting up, you know, why are 22 people doing case-control studies 23 in the first place, because they 24 have, like, lower level of</p>	<p style="text-align: right;">Page 320</p> <p>1 identification as Exhibit 2 Ballman-20.) 3 BY MR. TISI: 4 Q. It's entitled "Six 5 Persistent Research Misconception." 6 Do you see that? 7 A. Yes, I do see that. 8 Q. Have you seen this article 9 before? 10 A. You know, I think in my 11 career I have seen this article before. 12 Q. Okay. And again, 13 Dr. Rothman you would agree, he's the 14 founder of the Journal of Epidemiology. 15 You understand that, correct? 16 MS. MILLER: Objection. 17 THE WITNESS: I have no idea 18 if he's the founder of the Journal 19 of Epidemiology. 20 BY MR. TISI: 21 Q. This is a fairly well known 22 article, correct? 23 A. I don't know that either. 24 Q. Okay. Well, let's look at</p>
<p style="text-align: right;">Page 319</p> <p>1 evidence than cohort studies. I 2 just -- I can't really comment if 3 I agree or disagree with that. 4 BY MR. TISI: 5 Q. Okay. You can't agree or 6 disagree with that statement. 7 A. Well, with the limited 8 information -- I'm given a couple 9 sentences that I'm asked to look at out 10 of an entire chapter that comes out of an 11 entire book, I do not feel that I can 12 give a complete and truthful answer. 13 Q. Let's see if this helps. 14 Okay. I'm going to show you an article 15 that Dr. Rothman wrote on this very 16 topic. 17 MS. MILLER: Are we done 18 with this exhibit? 19 MR. TISI: For now. You 20 can put it to aside. You can 21 leave the book there if you like 22 to. You can refer to it if you 23 need to. 24 (Document marked for</p>	<p style="text-align: right;">Page 321</p> <p>1 Misconception Number 1, because actually 2 as opposed to reading the whole article, 3 which I'm more than happy to have you 4 take a look at if you'd like to, but 5 Misconception Number 1, would you read 6 that? He puts a bullet point there. 7 Would you please tell the judge and the 8 jury what he says is Misconception Number 9 1. Read that, please. 10 A. I'll read what he says. He 11 says, "The misconceptions are, number 12 one, there is a hierarchy of study 13 designs, randomized trials provide the 14 greatest validity" -- and he's talking 15 validity there -- "followed by cohort 16 studies, with case-control studies being 17 the least reliable." 18 Q. Okay. He calls that a 19 misconception, does he not? 20 A. You know, I don't know what 21 he means by validity, and I don't know 22 what he means by least reliable. I'm 23 talking about levels of evidence. So I 24 don't know if those terms mean exactly</p>

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<p>1 the same thing.</p> <p>2 Q. Okay. Let's see what he</p> <p>3 actually says. Does he say -- in the</p> <p>4 first paragraph he talks about RCT, first</p> <p>5 two paragraphs. Let's talk about the</p> <p>6 next paragraph.</p> <p>7 It says, "Both cohort and</p> <p>8 case-control studies will yield valid</p> <p>9 results when properly designed and</p> <p>10 carried out."</p> <p>11 Do you see that?</p> <p>12 A. Where it is again? Again,</p> <p>13 you're making me come -- you know, go</p> <p>14 through a whole lot of information and</p> <p>15 so --</p> <p>16 Q. Well, you know, I'm going to</p> <p>17 tell you, if you feel like you need to</p> <p>18 take a look at this entire misconception,</p> <p>19 feel free to do it.</p> <p>20 A. So, I mean, I'm surprised --</p> <p>21 I just want to point out a couple things</p> <p>22 and --</p> <p>23 Q. No, I don't -- there's no</p> <p>24 question pending. You said you wanted to</p>	<p>1 second-to-last paragraph on the first</p> <p>2 column.</p> <p>3 A. Okay. Thank you.</p> <p>4 Q. It says, "Discrepancies</p> <p>5 between cohort studies and case-control</p> <p>6 studies should not be explained away</p> <p>7 superficially by a presumed validity</p> <p>8 advantage for cohort studies over</p> <p>9 case-control studies."</p> <p>10 Does he not say that?</p> <p>11 A. That's what is written</p> <p>12 there.</p> <p>13 Q. Okay. And if you go --</p> <p>14 A. And I want to point out --</p> <p>15 and he goes on and says, "Properly</p> <p>16 designed case-control studies will</p> <p>17 produce the same results as properly</p> <p>18 designed cohort studies."</p> <p>19 So what that means is the</p> <p>20 studies need to not have recall bias and</p> <p>21 they need not to have selection bias,</p> <p>22 which is almost theoretically impossible</p> <p>23 to do.</p> <p>24 Also, this is the only</p>
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<p>1 take a look at it. Feel free to take a</p> <p>2 look at it, and I'll ask you questions</p> <p>3 about it.</p> <p>4 A. Okay.</p> <p>5 Q. I want to be fair.</p> <p>6 A. All right. Go ahead.</p> <p>7 Q. Does he not say, in the</p> <p>8 second paragraph, "Both cohort studies</p> <p>9 and case-control studies will yield a</p> <p>10 valid result when properly designed and</p> <p>11 carried out"?</p> <p>12 A. That's what he says.</p> <p>13 Q. Okay. Now, I'm going to</p> <p>14 read -- he says, "Similarly" -- on the</p> <p>15 next page, second-to-last paragraph,</p> <p>16 "Similarly, discrepancies between cohort</p> <p>17 studies and case-control studies should</p> <p>18 not be explained away superficially by a</p> <p>19 presumed validity advantage for cohort</p> <p>20 studies over case-control studies."</p> <p>21 True?</p> <p>22 A. I'm sorry. Where are you</p> <p>23 reading from again?</p> <p>24 Q. The next -- the</p>	<p>1 author out there that has written on</p> <p>2 this, is one textbook, same author, one</p> <p>3 paper, same author. And the author goes</p> <p>4 on to, say, "These misconceptions have</p> <p>5 been perpetuated in journals, classrooms</p> <p>6 and textbooks."</p> <p>7 And so I could do the same</p> <p>8 thing and find a vast majority more</p> <p>9 papers and textbooks and so forth that</p> <p>10 would dispute that.</p> <p>11 Q. But you didn't, Doctor. You</p> <p>12 didn't even cite it for any -- for any of</p> <p>13 the times. We went through your report,</p> <p>14 and you didn't cite one instance. You</p> <p>15 said one article that was in a different</p> <p>16 place, case-control -- case-control</p> <p>17 textbook. And I'm going to look that up.</p> <p>18 Okay. But other than that,</p> <p>19 you had no citations whatsoever, true?</p> <p>20 MS. MILLER: Objection.</p> <p>21 THE WITNESS: I disagree</p> <p>22 with that, because if we go back</p> <p>23 to -- to my report, I have -- I</p> <p>24 have like real evidence in the</p>

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<p>1 literature that shows that 2 case-control studies do, and 3 cohort studies do not -- when you 4 do -- have the opportunity to do a 5 randomized trial, it comes up with 6 a completely different conclusion. 7 And I have several 8 references that show that. And 9 that's real life data. That's not 10 purporting, you know, evidence 11 against what's a generally 12 accepted epidemiology principle. 13 BY MR. TISI: 14 Q. Let's look at the last 15 sentence in this section. It says, "When 16 properly designed" -- 17 A. And, you know, this says 18 it's a review too. It doesn't say it's a 19 research article. This is, like, I think 20 someone's opinion. I mean -- 21 Q. Like your report. Like your 22 report. Your report is your opinion. 23 MS. SHARKO: Don't interrupt 24 the witness.</p>	<p>1 I'm allowed to -- to give the 2 complete truth. 3 BY MR. TISI: 4 Q. Okay. 5 A. I feel like we're doing half 6 truths here. 7 Q. Okay. I'm perfectly happy 8 to stand on this article. 9 Let me -- let me look at the 10 last sentence. "When properly designed 11 case-control studies can achieve" -- "can 12 achieve the same excellent validity as 13 properly designed cohort studies, whereas 14 poorly designed trial can be unreliable. 15 The type of study should be not taken as 16 a guide to the study's validity." 17 Does he not say that? 18 A. He does say that there. 19 Q. Okay. Thank you. Do you 20 agree or disagree? 21 A. I disagree with his -- his 22 entire thing. I think for individual 23 studies there could be an individual 24 case-control study that might be better</p>
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<p>1 BY MR. TISI: 2 Q. Your report is your opinion, 3 right? 4 MS. MILLER: Objection. 5 THE WITNESS: Those are two 6 different things. 7 BY MR. TISI: 8 Q. One is for litigation, and 9 one isn't? 10 MS. MILLER: Objection. 11 BY MR. TISI: 12 Q. Dr. Ballman, you know, 13 you're offering a lot of commentary of 14 things that I haven't asked. Okay? 15 I'm asking you, first of 16 all, this is published in the peer 17 reviewed literature, correct? 18 MS. MILLER: Objection. 19 MR. LOCKE: Objection. 20 THE WITNESS: So I think I'm 21 trying to give a complete and 22 truthful answer which I swore to 23 at the beginning of the 24 deposition, and I don't feel like</p>	<p>1 designed than an individual cohort study. 2 But I think as a body of 3 evidence as a whole, it is accepted as a 4 principle in epidemiology literature, 5 that what comes out of case-control 6 studies in total and what comes out of 7 cohort studies in total, are both under 8 randomized trials, and cohort studies 9 have less biases in terms of selection 10 biases and recall biases than do 11 case-control studies, which is why they 12 have a higher level of evidence. 13 Q. It has other biases too. 14 For example, if you only ask the 15 patient -- if the cohort study is not 16 designed to -- to look at a particular 17 question, and you only ask a person once 18 in 25 years whether they use talcum 19 powder, that can change over time, 20 correct? 21 A. So -- so what's the 22 question? 23 Q. The question is: That's a 24 bias as well, that would bias towards the</p>

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<p>1 null?</p> <p>2 MS. MILLER: Objection.</p> <p>3 BY MR. TISI:</p> <p>4 Q. If a patient, in a</p> <p>5 hypothetical cohort study, that was not</p> <p>6 designed specifically to look at whether</p> <p>7 talc causes ovarian cancer, and that</p> <p>8 patient -- and it's a 20-year study, and</p> <p>9 upon enrollment they are asked one time</p> <p>10 about their exposure to talc, is it</p> <p>11 possible that over two decades, the</p> <p>12 patient could change their behavior?</p> <p>13 MS. MILLER: Objection.</p> <p>14 There were three questions in</p> <p>15 there. I objected to the first.</p> <p>16 MR. TISI: There's not --</p> <p>17 that's fine. You can object --</p> <p>18 you can object to the question.</p> <p>19 MS. MILLER: Okay. I don't</p> <p>20 know what the question is.</p> <p>21 MR. TISI: That's fine.</p> <p>22 THE WITNESS: Can you ask</p> <p>23 one by one what -- what the --</p> <p>24 BY MR. TISI:</p>	<p>1 could -- could make comment on them.</p> <p>2 Q. In all the cohort studies</p> <p>3 regarding talc, the patients were asked</p> <p>4 on only one occasion whether they used</p> <p>5 talc early on in the study, correct?</p> <p>6 A. So the cohort --</p> <p>7 MR. LOCKE: Objection.</p> <p>8 THE WITNESS: So the cohort</p> <p>9 studies in talc were done in -- in</p> <p>10 cohorts of women that tended to be</p> <p>11 older. And -- and I can go</p> <p>12 through the different cohorts.</p> <p>13 BY MR. TISI:</p> <p>14 Q. I'm asking -- I didn't ask</p> <p>15 you to -- to recite me. I'm asking you,</p> <p>16 in each of those studies, the women</p> <p>17 enrolled in those studies were asked</p> <p>18 about talc exposure on one occasion,</p> <p>19 true?</p> <p>20 MR. LOCKE: Objection.</p> <p>21 THE WITNESS: So I was</p> <p>22 trying -- and your previous</p> <p>23 question I think was a little bit</p> <p>24 different and I was trying to</p>
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<p>1 Q. You understand that there</p> <p>2 are biases that are also inherent in</p> <p>3 cohort studies as well?</p> <p>4 A. I -- I think I'm pretty --</p> <p>5 pretty clear that I think all</p> <p>6 observational studies have some sort of</p> <p>7 biases in them.</p> <p>8 Q. Right. And you have to</p> <p>9 consider all of them, correct?</p> <p>10 A. All of what?</p> <p>11 Q. All the biases and all the</p> <p>12 different kinds of studies.</p> <p>13 A. You have to consider -- I --</p> <p>14 I looked -- I don't know what that means.</p> <p>15 Q. You don't dismiss biases in</p> <p>16 cohort studies because they happen to be</p> <p>17 cohort studies, right?</p> <p>18 A. Again, it depends upon what</p> <p>19 the individual studies are and the</p> <p>20 question that is being addressed with the</p> <p>21 cohort study so that we can see what the</p> <p>22 individual biases are --</p> <p>23 Q. Right.</p> <p>24 A. -- and then, you know, one</p>	<p>1 answer that before you interrupted</p> <p>2 me with -- with the second</p> <p>3 question, and so --</p> <p>4 BY MR. TISI:</p> <p>5 Q. Okay. Then let me withdraw</p> <p>6 the question.</p> <p>7 I'm going to ask you, can</p> <p>8 you name for me a cohort study --</p> <p>9 MS. MILLER: You just</p> <p>10 interrupted her again. She was</p> <p>11 like literally -- when she says</p> <p>12 "and so," you start talking. Let</p> <p>13 her finish her sentences.</p> <p>14 MR. TISI: I'm going to</p> <p>15 ask -- I'm going to ask -- I</p> <p>16 withdrew the question.</p> <p>17 BY MR. TISI:</p> <p>18 Q. My question is this --</p> <p>19 MS. MILLER: You can't just</p> <p>20 withdraw a question in the middle</p> <p>21 of an answer.</p> <p>22 BY MR. TISI:</p> <p>23 Q. Doctor, can you name me one</p> <p>24 cohort study involved in the talc science</p>

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<p>1 where the patients were asked more than 2 once about their talc exposure? 3 A. I cannot, but I'm not -- I'm 4 trying to say why that's not really a 5 relevant question. 6 Q. Okay. I just want to know 7 if they were asked more than once in any 8 of these studies. 9 A. They weren't asked more than 10 once in the case-control studies either. 11 Q. Well, that was only because 12 they were retrospective, right? 13 A. Well, there are reasons why 14 that asking only once in the cohort study 15 also is not entirely relevant. 16 Having to do with at the age 17 that women generally start using talc, 18 which is early adulthood, and the fact 19 that it's a habitual use and it's very 20 unlikely that a woman age, say 55, who 21 hadn't been using talc would all of the 22 sudden start using talc. 23 Q. Are you -- do you think that 24 you're a better qualified epidemiologist</p>	<p>1 idea and I don't know what the 2 relevance is in terms of -- of me 3 having issues -- or the 4 limitations of this particular 5 study. 6 BY MR. TISI: 7 Q. Well -- well, then let me -- 8 let me -- 9 MR. SOILEAU: Let me do this 10 and fix this, because we may have 11 gotten off. I don't think -- 12 MS. SHARKO: I thought only 13 one person -- 14 MR. SOILEAU: I'm doing 15 exhibits. I'm not asking 16 questions. 17 MR. TISI: It's an exhibit 18 issue. 19 MS. SHARKO: But I'm happy 20 to have you talk. That's okay. 21 MR. SOILEAU: I'm just going 22 to -- I think we agreed that we 23 had 18 as the Viagra report, 19 as 24 Chapter 8 of the Rothman text.</p>
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<p>1 than Ken Rothman is? 2 MR. LOCKE: Objection. 3 MS. MILLER: Objection. 4 What's with these questions? 5 THE WITNESS: I'm not 6 speaking on -- I'm not speaking on 7 qualifications or not. 8 I'm speaking on the fact 9 that there -- this is probably one 10 of the only papers that -- that 11 takes this stance that the general 12 accepted principles of 13 epidemiology are wrong. 14 BY MR. TISI: 15 Q. Do you know -- do you know 16 that Dr. Rothman was actually -- unlike 17 you, Dr. Rothman was actually asked by 18 the talc industry, including Johnson &amp; 19 Johnson, to consult for them on the 20 talc-ovarian cancer association, did you 21 know that? 22 MR. LOCKE: Objection. 23 MS. MILLER: Objection. 24 THE WITNESS: I -- I have no</p>	<p>1 And I do not believe in the 2 record that the "Six Persistent 3 Research Misconceptions" that has 4 been discussed over the last pages 5 with the witness was actually 6 identified by number. 7 It has a sticker on it 8 that's wrong. It should be 9 Exhibit 20. 10 MS. MILLER: It says 19. Do 11 you want to make it 20? 12 MR. SOILEAU: Yeah, here's a 13 sticker. You can just stick it 14 over the top of it. 15 MS. MILLER: I wrote 20 16 right over it. 17 MR. SOILEAU: Okay. Very 18 good. And I apologize for 19 interrupting. 20 (Document marked for 21 identification as Exhibit 22 Ballman-21.) 23 MR. TISI: I'd like to show 24 you Exhibit Number 24.</p>

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<p>1 MS. MILLER: Wait. 21? 2 MR. TISI: 21. I'm sorry. 3 21. 4 MS. MILLER: You just 5 skipped 21, 22, 23. 6 MR. TISI: I'm sorry. 7 You're right. 8 BY MR. TISI: 9 Q. I'm going to represent to 10 you, Doctor, that Dr. Rothman and his 11 colleagues were asked to draft a report 12 for the national toxicology program in 13 2000 related to talc and ovarian cancer. 14 Have you seen this before? 15 A. Now is this published 16 somewhere? 17 Q. It was for the talc industry 18 including Johnson &amp; Johnson. They 19 actually contributed to paying for it. 20 MR. LOCKE: Objection. 21 THE WITNESS: Sort of like 22 an expert report is in litigation? 23 BY MR. TISI: 24 Q. Sort of like -- absolutely</p>	<p>1 BY MR. TISI: 2 Q. Dr. Ballman -- 3 A. Yes. 4 Q. Unlike you, the scientists 5 at Johnson &amp; Johnson, reached out to 6 Dr. Rothman in 2000 to draft a report 7 related to talc. Do you see that? 8 MR. LOCKE: Objection. 9 THE WITNESS: I -- can you 10 show me where this was 11 commissioned by Johnson &amp; Johnson? 12 BY MR. TISI: 13 Q. I'm going to ask you to -- 14 I'm going to ask you to assume that, 15 because that's what the record will show. 16 This was a report submitted to the 17 National Toxicology Program on the part 18 of J&amp;J? 19 MR. LOCKE: Objection. 20 BY MR. TISI: 21 Q. So let me -- let me show 22 you. 23 A. But where does it say that? 24 Where does it say the National</p>
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<p>1 absolutely. Sort of like that. Like 2 in -- 3 A. Like I've been asked to do? 4 Q. Like in real time, when the 5 issues were -- but the difference is, 6 see, they were asked by scientists at 7 Johnson &amp; Johnson that they contacted 8 Dr. Rothman. It's the lawyers who 9 contacted you. 10 MS. MILLER: Objection. Was 11 that a question or are you just 12 giving speeches now? 13 MR. TISI: Well, no, she's 14 giving me a speech. 15 MS. MILLER: She's -- she's 16 sitting -- 17 MS. SHARKO: The witness -- 18 you know, it's really rude to call 19 a woman "she." 20 MR. TISI: Okay. 21 MS. SHARKO: Her name is 22 Dr. Ballman, and I would ask you 23 to treat the witness with respect. 24 MR. TISI: Okay.</p>	<p>1 Toxicology -- 2 Q. I'm asking you to assume it. 3 I'm allowed -- I'm allowed to ask you to 4 assume it. And counsel will correct me 5 later if I'm wrong. 6 A. Okay. 7 Q. The judge will strike me. 8 A. Okay. 9 Q. Okay? 10 MS. MILLER: I don't know if 11 the judge will actually strike 12 you. 13 BY MR. TISI: 14 Q. So on Page 3 -- on Page 3, 15 Dr. Rothman and his two colleagues -- 16 this wasn't just written by him, right? 17 A. But again, Dr. Rothman, it's 18 not independent of Dr. Rothman. 19 Q. Okay. That's fine. He 20 writes, "Exposure misclassification." 21 Do you see that section? 22 A. Yes. 23 Q. Okay. He says this: 24 "Nearly all the studies were case-control</p>

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<p style="text-align: right;">Page 342</p> <p>1 studies. It is commonly believed that 2 the validity of case-control studies is 3 worse than cohort studies, but this view 4 is mistaken." 5 Do you see that? 6 A. Yes, I do. 7 Q. Okay. And you disagree with 8 that? 9 A. Again, it's the same opinion 10 by the same individual and -- and I have 11 stated that the general principles of 12 epidemiology just does not support that. 13 Q. Okay. And the next 14 sentence, "The validity of a study design 15 depends on the specifics of the study 16 design. The nature of the data and the 17 nature of the hypothesis that the study 18 addresses." 19 Do you agree with that? 20 A. So now he's getting into 21 specifics. And I said I do agree that 22 one case-control study when compared to 23 one cohort study could be the case that 24 the case-control study is done a little</p>	<p style="text-align: right;">Page 344</p> <p>1 A. -- in terms of the habits. 2 I don't know, I haven't 3 looked at this literature. So I'd have 4 to look to see. Do most coffee drinkers 5 start when they're in their early 6 adulthood? Do most -- versus starting at 7 age 55. You know, it all depends on the 8 specifics of the study. 9 Q. The last two sentences here, 10 state what I think his -- his rule is. 11 "The effect of having a poor measure of 12 exposure will be considerable 13 nondifferential misclassification. A 14 type of error that introduces bias into 15 study results that tends to drive effect 16 estimates towards the null condition of 17 no effect. 18 "In contrast, it may be 19 possible to get more detailed information 20 from a study subject in a case-control 21 study which might avoid some of the 22 biases that would result in the cohort 23 study." 24 Do you see that?</p>
<p style="text-align: right;">Page 343</p> <p>1 better than the one cohort study. But 2 I'm arguing that -- I'm not arguing. I'm 3 sorry. 4 I'm just stating what the 5 general epidemiology principle is, is 6 that cohort studies, as a whole, have a 7 higher level of evidence for causality 8 than do case-control studies. 9 Q. He makes the point, if you 10 go next sentence -- he gives an example. 11 Next sentences says, "Although the 12 exposure information might be accurate at 13 the time that it was collected, the 14 exposure status of cohort members will 15 change with time and the initial measure 16 might only be poorly correlated with a 17 more meaningful measure." 18 Do you see that? 19 A. And -- but this has to do in 20 particular with coffee drinkers and a 21 one-time dietary assessment. So drinking 22 coffee or not is different from whether 23 one uses talcum powder or not -- 24 Q. Why?</p>	<p style="text-align: right;">Page 345</p> <p>1 MR. LOCKE: Objection to 2 form and to the reference to the 3 last two sentences. 4 MS. MILLER: I'm sorry. I 5 can't hear you. 6 MR. LOCKE: Objection to 7 form and the reference to the last 8 two sentences. 9 BY MR. TISI: 10 Q. Read it to yourself. Do you 11 agree or disagree with those last two 12 sentences? 13 A. It's just a very general 14 statement. I'm not sure what to agree 15 with or not to agree with. Again, I 16 think it depends very much on what the 17 question that's under consideration or 18 the study under consideration. And I 19 have to point out that says, "Which might 20 thus avoid some of the biases that would 21 result in a cohort study." 22 It doesn't say will. It 23 doesn't say anything definitive. It says 24 might.</p>

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<p>1 Q. But that's the point, 2 Doctor. And I'm really trying to back up 3 a little bit. 4 The point really here is, 5 what you really have to do is look at the 6 data and look at the studies, the cohort 7 and the case-control studies like you 8 said in your Viagra report. You look at 9 them together, and you decide which one 10 is better and which one is worse, true? 11 MS. MILLER: Objection. 12 That -- where did she say that in 13 the Viagra report that you should 14 look at them together? Can you 15 show that us? Because you showed 16 us part of the report. It didn't 17 say that. You're misrepresenting 18 her testimony. 19 MR. TISI: Counsel, please 20 stop. 21 MS. MILLER: You're 22 misrepresenting her report. This 23 is crazy. 24 MR. TISI: Stop. It is</p>	<p>1 did not show a statistically significant 2 result, whereas in the case-control 3 studies, some did, some didn't. And by 4 levels of -- as I say throughout my 5 report, as levels of evidence, one needs 6 to go with the cohort studies because 7 they have a higher level of evidence. 8 I'm not comparing one individual cohort 9 study to one individual case-control 10 study, where it might be the case that in 11 that particular comparison of two 12 different studies, maybe case-control was 13 done a little better than cohort. 14 Q. So -- okay. So we'd talked 15 about statistical significance in a short 16 while. 17 So but -- so what you're 18 saying is where there is a -- if you have 19 some studies that are cohort studies that 20 are not statistically significant and 21 some studies that are case-controls that 22 are statistically significant, the cohort 23 studies win? 24 MS. MILLER: Objection.</p>
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<p>1 crazy. What is crazy is your 2 speaking/coaching objections. 3 That's crazy. 4 BY MR. TISI: 5 Q. Doctor, in your case -- in 6 your Viagra report you put case-control 7 and cohort studies in the same level of 8 evidence, did you not? 9 A. I do not believe I do. 10 Q. Okay. 11 A. I was just given one case 12 where -- where I -- no, I do not believe 13 I do. 14 Q. Okay. Now, isn't it true 15 that you're really, instead of just 16 blindly saying cohort is better than 17 case-control, you have to look at the 18 studies, how they're designed, what they 19 ask, and what the data shows; isn't that 20 true? 21 A. And that's what I did, and I 22 applied underlying epidemiological 23 principles. And so there were three 24 cohort studies, not just one. All three</p>	<p>1 THE WITNESS: I am -- not in 2 general. I am saying -- no, I did 3 not say that in general. I said 4 in the data and the analyses I 5 looked at, that was one component 6 of the whole totality of the 7 analyses. 8 BY MR. TISI: 9 Q. Okay. And statistical 10 significance was very important to you in 11 that way, in other words you kind of 12 put -- you saw whether there's a pattern. 13 You put together the statistically 14 significant results, the statistically 15 nonsignificant results, and you felt that 16 the statistically nonsignificant results 17 had the better reliability? 18 A. Again, I don't -- what I did 19 was I looked at the totality of the data. 20 I saw in the case-control studies, there 21 were some statistically significant and 22 some not statistically significant. 23 I did not group those with 24 the cohort studies which also were not</p>

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<p>1 statistically significant. So I do not 2 believe that I just sort of put all the 3 nonstatistically significant studies 4 together and the statistically 5 significant studies together. I do not 6 believe that's what I did. 7 Q. Do you think statistical 8 significance is the issue that is the -- 9 defines your opinion? In other words -- 10 in other words, where you feel that there 11 is inconsistency between the 12 observational data, because some studies 13 were not statistically significant and 14 others were. 15 MS. MILLER: Objection. 16 BY MR. TISI: 17 Q. True? 18 MS. MILLER: Objection. 19 THE WITNESS: I don't 20 believe that's what I stated. And 21 I believe I stated all along that 22 I did the Bradford Hill analyses. 23 You know, I looked at strength of 24 association. I looked at</p>	<p>1 The hospital-based controls, none of them 2 were statistically significant. And 3 those were case-control studies. You 4 know, so you look at the different study 5 designs, and you're getting different 6 sort of results, and that's an 7 inconsistency. 8 Q. Okay. And so they're 9 inconsistent in that some are 10 statistically significant and others 11 aren't? 12 MS. MILLER: Objection. 13 THE WITNESS: Again, taken 14 as a whole -- and I also talk 15 about the fact that if you look at 16 the magnitude of the estimates -- 17 BY MR. TISI: 18 Q. We'll talk about that. 19 A. -- that were produced -- 20 well, that has to do with consistency 21 too. 22 Q. I'm going to talk about -- I 23 need to -- 24 A. Well, no, you asked me if my</p>
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<p>1 consistency. And I made a note in 2 terms of consistency that there 3 was no consistency on many -- a 4 lack of consistency on many 5 different levels. 6 BY MR. TISI: 7 Q. Okay. Are you done? 8 MS. MILLER: Are you -- are 9 you still talking? 10 THE WITNESS: So this 11 factor -- so consistency is that, 12 you know, it needs to be multiple 13 studies across different locations 14 and populations, and study designs 15 have to show a similar association 16 between the exposure and outcome. 17 I would also note within the 18 case-control studies -- 19 BY MR. TISI: 20 Q. Can I -- can I ask you -- 21 A. -- the hospital-based -- 22 Q. -- a question here? Can I 23 ask you -- 24 A. I'm not finished, please.</p>	<p>1 consistency is just on the basis if -- 2 Q. I didn't. 3 A. -- there's statistical 4 significance or not. 5 Q. Doctor, you know, when I 6 ask -- when I ask a question, it involves 7 different variables, I get accused of 8 asking a compound question. So I'm 9 asking you one question at a time. 10 Is statistical significance, 11 when you looked at these studies overall, 12 did you find that the statistically 13 significant results were counter-balanced 14 by the statistically insignificant 15 results? 16 MS. MILLER: Objection. 17 THE WITNESS: I do not -- 18 I'm sorry. 19 I do not know what you mean 20 by counterbalance. 21 BY MR. TISI: 22 Q. In other words, did they 23 negate them? 24 MS. MILLER: Objection.</p>

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<p>1 THE WITNESS: That's not 2 what I said. 3 BY MR. TISI: 4 Q. Are they inconsistent with 5 them? Is it inconsistent that some 6 studies are statistically significant and 7 others aren't? 8 A. Again, consistency requires 9 that multiple studies across different 10 locations, populations, and study designs 11 show similar association between the 12 exposure and the outcome. 13 So I looked at case-control 14 studies, which is one design. And within 15 case-control studies you have 16 population-based case-control studies, 17 which is a design. You have 18 hospital-based control studies, which is 19 a design. 20 You also have cohort 21 studies, which is another different 22 design. 23 And when you look across 24 that, you do not come up with the same</p>	<p>1 A. I didn't say that they 2 shouldn't be done. But to be done 3 correctly and how to look at them 4 correctly, and -- is to do a separate 5 case -- meta-analyses of the case-control 6 studies, and a separate of the cohort 7 studies, and not just do one case -- or 8 one meta-analysis that combine both 9 together. 10 And a lot of the 11 meta-analysis, they do report out 12 separately for the case-control studies 13 and the cohort studies. 14 Q. But they do a meta-analysis 15 combining all the studies, every single 16 one of them combine all the studies? 17 MS. MILLER: Objection. 18 THE WITNESS: Yes. And I 19 have -- I do know that I have 20 citations in here somewhere that 21 shows that that is a problem with 22 meta-analysis. Because it lumps 23 over -- you won't be able to see 24 consistency or not, but you -- you</p>
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<p>1 association. 2 Q. Isn't that why you do a 3 meta-analysis? 4 A. No. 5 Q. Okay. Well -- 6 A. Meta-analysis -- let me 7 answer -- finish that. 8 Meta-analyses are not meant 9 that if results differ from each other 10 you throw them all together to get a 11 result that you want. And in fact if 12 results are different from each other, 13 you shouldn't do a meta-analyses. That's 14 heterogeneity -- 15 Q. So you think -- 16 A. -- and that's going to lead 17 to an incorrect conclusion. 18 Q. So you think nobody -- 19 MS. MILLER: Are you done? 20 THE WITNESS: I'm done. 21 BY MR. TISI: 22 Q. So you think that -- there 23 are five or six meta-analyses. Do you 24 think those shouldn't have been done?</p>	<p>1 just have one result. So you 2 can't see where the results 3 differ. 4 BY MR. TISI: 5 Q. Now, in criticize -- 6 MS. MILLER: Is this a good 7 time for a break? 8 MR. TISI: No. Unless you 9 need it. Do you need it? 10 MS. MILLER: Do you need it? 11 THE WITNESS: I need it. 12 MS. MILLER: It's not about 13 me. It's about her. 14 MR. TISI: Absolutely. If 15 she needs it, she can always ask 16 for it. 17 THE WITNESS: Yeah, I'm 18 sorry. I was trying to be polite. 19 Thank you. 20 MS. MILLER: Yeah, she's 21 very polite. She's not going to 22 ask. 23 THE VIDEOGRAPHER: Stand by, 24 please. The time is 2:23 p.m.</p>

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<p>1 Off the record. 2 (Short break.) 3 THE VIDEOGRAPHER: Okay. We 4 are back on the record. The time 5 is 2:34 p.m. 6 BY MR. TISI: 7 Q. In your report -- Doctor, 8 we're talking about the talc studies 9 now -- you have some criticisms of the 10 plaintiffs' experts in how they addressed 11 the biases in the cohort studies and you 12 give your opinions about them, and it's 13 pretty clear in your report. You know 14 that section, correct? 15 MS. MILLER: Is that a 16 question? 17 MR. TISI: Yes. 18 THE WITNESS: Can you point 19 me to the section, please? 20 BY MR. TISI: 21 Q. Sure. I'm happy to do that. 22 On Page 28. Do you see you're addressing 23 the issues that the plaintiffs' experts 24 raise about the cohort studies and you</p>	<p>1 A. It's why I disagree with the 2 methodology. 3 Q. Okay. And for the record, 4 the cohort studies are what? Gertig, 5 Gates, Houghton and Gonzales? 6 A. Yeah, it depends on how you 7 count cohort studies. But those are 8 publications on the cohort studies. 9 Q. And so it's not that the 10 plaintiffs' experts don't consider the 11 cohort studies, they just think that on 12 balance they're not as reliable as -- 13 MR. TISI: What are you 14 shaking your head for? 15 MS. MILLER: Because 16 you're -- okay, I'll wait. I'll 17 object at the end. I didn't mean 18 to be shaking my head. 19 MR. TISI: You've been doing 20 it the whole time. 21 MS. MILLER: There's a video 22 that will -- 23 MR. TISI: It will. 24 BY MR. TISI:</p>
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<p>1 address them and your opinions about them 2 are pretty clear. 3 A. So you're talking about the 4 paragraph that says, "The final argument 5 made by plaintiffs' experts"? 6 Q. Yeah. Actually and it 7 starts -- you talk about all of the -- 8 you address all of the issues that -- I 9 mean, this is not a trick question. 10 A. Yeah. 11 Q. You are addressing all of 12 the issues that the plaintiffs' experts 13 raise about the cohort studies here, and 14 you don't think that they're valid, and 15 you give the reasons for that, correct? 16 MS. MILLER: Objection. 17 Objection. 18 THE WITNESS: So yeah, you 19 know, as it says here, I -- I say 20 plaintiffs cite certain things, 21 and I point out why I disagree 22 with their methodology. 23 BY MR. TISI: 24 Q. Okay. In your opinion?</p>	<p>1 Q. So the question is not -- 2 your contention is not that the 3 plaintiffs' experts don't address the 4 cohort studies. You just disagree about 5 the interpretation that they give to the 6 cohort studies; is that fair? 7 MS. MILLER: Objection. 8 Objection. 9 THE WITNESS: My concern is 10 the methodology used by the 11 plaintiffs in doing their -- their 12 whole analyses of the data in 13 total. 14 BY MR. TISI: 15 Q. And what methodology do you 16 think that they used wrong with respect 17 to the cohort studies? 18 A. I -- well, again, I think 19 that they -- in terms of the methodology, 20 I was talking about methodology, sort of 21 in general. I don't think that they're 22 applying the Bradford Hill criteria in a 23 methodologically correct manner. 24 And so for the cohort</p>

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<p>1 studies, I point out, you know, what they 2 say as to why, you know, they say that, 3 well, the cohort studies, you know, 4 really have no play in terms of 5 determining consistency. 6 Q. Is that what you think they 7 say? 8 A. I'm paraphrasing. I do 9 not -- I do not see -- I don't know 10 offhand, and I'll have to read through 11 carefully. But it's I seem to remember 12 that none of the plaintiffs' experts said 13 that -- that they gave cohort studies 14 more weight than they did the 15 case-control studies. 16 Q. And you think that they 17 should have said cohort studies should be 18 given more weight than case-control 19 studies? 20 A. I'm -- 21 MS. MILLER: Objection. 22 THE WITNESS: I'm saying -- 23 MS. MILLER: Please give me 24 time to object. I know everybody</p>	<p>1 plaintiffs' experts, there's several of 2 them. There's misclassification bias 3 that they identified. You know what that 4 is, right? 5 A. Can you point in particular 6 where they identified a mis -- 7 Q. Well, I'm asking you. You 8 identified it in your report. You said 9 that one of the issues that were raised 10 was that they did not -- the issue that 11 Dr. Rothman raised -- 12 MS. MILLER: Do you want to 13 tell us what page you are reading? 14 MR. TISI: Page 28. 15 MS. MILLER: That would help 16 a lot. 17 MR. TISI: I'm on Page 28. 18 I told you before. 19 THE WITNESS: Yeah, yeah, 20 but I don't know from there where 21 you're reading. 22 BY MR. TISI: 23 Q. Okay. Let me ask you this. 24 Did they identify misclassification bias?</p>
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<p>1 is tired this afternoon. 2 BY MR. TISI: 3 Q. I mean, I'm reading what 4 you. You said, "I don't know offhand but 5 I'll have to read through carefully. But 6 it seemed -- I seem to remember that none 7 of plaintiffs' experts said that they 8 gave cohort studies more weight than they 9 did case-control studies." 10 And you think that's a 11 methodologic flaw? 12 A. I -- I -- in the end I may 13 be misremembering exactly what they said. 14 But I do believe some of them said I 15 weighted the case-control studies more 16 because here are flaws in the cohort 17 studies and that sort of makes them 18 invalid. 19 And due to the generally 20 accepted principle in epidemiology that 21 cohort studies have higher evidence than 22 do case-control studies, I don't think 23 that's correct. 24 Q. But the biases that the</p>	<p>1 A. I don't know. I mean, can 2 you -- 3 Q. I'm asking you. You're the 4 expert. I'm just a lawyer. Did they 5 identify misclassification bias? 6 A. I'll have to go through all 7 the expert reports and see which ones. 8 Q. I'm asking, in your 9 report -- in your report, do you identify 10 that she would -- that the witness's 11 plaintiff were concerned about 12 misclassification bias? 13 A. I'll have to go through my 14 report. 15 MR. LOCKE: Objection to 16 form. Maybe it's just the 17 pronouns. But are you talking 18 about a specific witness? 19 MR. TISI: No. She's 20 lumping them altogether. 21 MS. MILLER: Where is she 22 lumping them altogether? 23 BY MR. TISI: 24 Q. Plaintiffs' experts. It</p>

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<p>1 says the final argument made by 2 plaintiffs' experts. 3 A. Yes. And I cite two of 4 them, so what is 15 and 73? 5 So one is, as I -- we've 6 been talking about, is that the level of 7 evidence in cohort studies is weaker than 8 that in case-control studies. 9 And number 15 and 73 are -- 10 so that would be McTiernan and Moorman. 11 Q. Okay. So now let me ask you 12 this. Do the witnesses -- do as a whole, 13 do the plaintiffs' experts, one, or all 14 of them, talk about the issue of 15 misclassification bias? 16 MS. MILLER: Objection. 17 THE WITNESS: I can't 18 remember off the top of my head. 19 BY MR. TISI: 20 Q. But you know what 21 misclassification bias is, right? 22 A. Yes, I do. 23 Q. What is it? 24 A. It's when you put a case</p>	<p>1 THE WITNESS: That's more of 2 a feasibility question and a 3 resource question. I don't see 4 how that creates any biases or 5 confounding or issues like that. 6 BY MR. TISI: 7 Q. One of the things that you 8 raised is that Narod had mentioned that 9 there should be 200,000 patients. Do you 10 remember that? 11 A. Yes, I do. We can look at 12 it here. 13 Q. Let me ask you. Did you 14 ever -- did you -- did you do any power 15 calculation to determine how big a cohort 16 study would have to be in order to 17 identify a risk of ovarian cancer? 18 MR. LOCKE: Objection. 19 BY MR. TISI: 20 Q. If you disagree -- if you 21 disagree with Dr. Narod? 22 MS. MILLER: Objection. 23 Is the question the first 24 one or is the second question?</p>
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<p>1 into the control group or you put a 2 control into the case group. 3 Q. Okay. And that is a 4 recognized bias and that's what 5 Dr. Rothman was talking about -- is a 6 recognized bias within -- within cohort 7 studies, correct? 8 A. It doesn't have to be just 9 cohort studies you can have 10 misclassification biases in case-control 11 studies. 12 Q. Okay. But that is a 13 recognized concern about cohort studies, 14 right? 15 A. It's something one needs to 16 be aware of when they are looking at 17 cohort studies. It doesn't mean that 18 every cohort study has misclassification 19 bias. 20 Q. Isn't it also another 21 concern that the studies -- that cohort 22 studies are difficult to design if 23 they're studying a rare disease? 24 MS. MILLER: Objection.</p>	<p>1 Is, "Do you disagree with 2 Dr. Narod a question?" Or is it 3 editorial content? What is that? 4 Objection. 5 MR. TISI: Thank you. 6 That's -- that's all you have to 7 say. 8 MS. MILLER: Well, I need to 9 know. 10 MR. TISI: You don't. 11 MS. MILLER: The witness 12 needs to know. 13 MR. TISI: She's doing just 14 fine. 15 MS. MILLER: Do you know 16 what the question is? 17 THE WITNESS: I'm not sure. 18 BY MR. TISI: 19 Q. Doctor -- 20 A. But I heard that I -- 21 Q. Because you were queued by 22 your lawyer, let me ask you this -- 23 MS. MILLER: It doesn't take 24 a queue to know.</p>

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<p>1 BY MR. TISI: 2 Q. You recall -- you recall -- 3 MR. TISI: Counsel, please. 4 BY MR. TISI: 5 Q. You recall that you -- that 6 Dr. Narod said that you would have to 7 have 200,000 patients in a cohort study 8 in order to detect -- detect ovarian 9 cancer, do you remember that? 10 A. We can go to the Narod 11 study. I just want to make sure exactly 12 what he said, but... 13 MS. MILLER: Is there a 14 specific part of her report that 15 you're referring to? 16 MR. TISI: I'll find it for 17 you. Honestly, she remembers it, 18 so you don't have to keep doing 19 that. 20 BY MR. TISI: 21 Q. Do you see in the middle of 22 Page 26 where it says, on your report, 23 "Across two different prospective 24 studies, there were approximately 1,400</p>	<p>1 A. I'm saying on the basis of 2 what we have here, I mean, if you read 3 that whole thing, it says, "Across the 4 three prospective studies there's 1,400 5 women with ovarian cancer, over 200,000 6 without." So if you take those numbers, 7 the power to detect a hazard ratio of 1.2 8 or larger is over 90 percent with a 9 two-sided level of significance of .05. 10 Q. Do you know whether or not 11 other people outside of litigation have 12 actually looked at the concerns about the 13 cohort studies that the plaintiffs' 14 experts have identified? 15 A. I'm not sure what the 16 question is. 17 Q. Well, I'll read it again. 18 A. I mean, is there a 19 publication that looked at the cohort -- 20 Q. Do you know whether or not 21 people -- people, scientists outside of 22 litigation, have looked at the issues 23 related to the talc cohort studies and 24 agreed with the plaintiffs?</p>
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<p>1 women diagnosed with ovarian cancer and 2 more than 200,000 women who were not 3 diagnosed with ovarian cancer." 4 Do you see that? 5 A. Yes. I see that. 6 Q. Okay. So now my question 7 is, did you do any power calculations to 8 determine how big the cohort studies 9 would have to be to detect ovarian 10 cancer, or are you relying on Narod? 11 A. I think if you go down. It 12 says the power to detect a hazard ratio 13 of 1.2 or larger is over 90 percent with 14 a two-sided level of confidence of 0.05. 15 Clearly this is sufficient power for an 16 association of 1.26 that is observed in 17 the case-control studies to be found 18 statistically significant. 19 So that -- so that is a 20 power statement. 21 Q. Okay. I'm asking you how 22 many patients would have to be enrolled 23 in a study. So what would that turn out 24 to be?</p>	<p>1 MS. MILLER: Objection. 2 THE WITNESS: I'm -- I mean, 3 the meta-analyses obviously looked 4 at the cohort studies, and I do 5 not remember -- 6 BY MR. TISI: 7 Q. Did you read the Taher? 8 A. The unpublished study that 9 hasn't been through peer review yet? 10 Q. Actually -- it's actually 11 been through peer review. But it's not 12 been published yet. You're correct. 13 But let me ask you -- 14 A. So there's a notification of 15 publication? 16 Q. Doctor, just I'm not 17 under -- I'm not under oath here. 18 A. Sorry. 19 Q. I'm asking you -- I'm asking 20 you this question? 21 A. Yeah. 22 MR. TISI: Are we laughing? 23 Is that part of -- part of 24 deposition protocol?</p>

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<p>1 MS. SHARKO: Well, you 2 represented that it was 3 peer-reviewed. 4 MR. TISI: I'm 5 representing -- 6 MS. SHARKO: And then you say 7 you're not under oath. Can we see 8 the peer review? Are you guys 9 part of that? 10 BY MR. TISI: 11 Q. Doctor -- Doctor -- 12 MR. TISI: I'm not part of 13 it, Counsel. You know I'm not 14 part of it. 15 MS. SHARKO: No, I don't. 16 BY MR. TISI: 17 Q. Do you know whether or not 18 the Taher authors have identified the 19 same weaknesses with the cohort study as 20 the plaintiffs' experts did? 21 A. I don't remember off the top 22 of my head -- 23 Q. Let's look at it. 24 A. -- but I would have sort of</p>	<p>1 was no question pending, Counsel. 2 BY MR. TISI: 3 Q. Okay. If you go to Page 43. 4 It says at the top, Although the reasons 5 are unclear, the difference potentially 6 due to issues related to latency, study 7 power or exposure misclassification. 8 And they're talking about 9 the difference between cohort and case 10 controls. 11 Do you see that? 12 A. I'm sorry, where were you 13 reading again? Was it starting 14 "although"? 15 Q. And the very top, "The 16 effect estimates of the meta-analysis 17 reported on 24-case-control studies" -- 18 A. Yes. 19 Q. -- "and three cohort studies 20 and refer to ever versus never use of 21 perineal talc. And it talks about the 22 fact that there's a difference between 23 the case-control and the cohort studies. 24 Do you see that?</p>
Page 375	Page 377
<p>1 the same... 2 MR. TISI: Yes, hers has the 3 tab. 4 MS. MILLER: Do you want 5 this tab? 6 BY MR. TISI: 7 Q. You read the -- you read 8 the -- 9 MR. TISI: Yes, I did that 10 to make her life easy. 11 (Document marked for 12 identification as Exhibit 13 Ballman-22.) 14 THE WITNESS: So this looks 15 like a draft. 16 BY MR. TISI: 17 Q. Yes, correct. 18 A. So whether it's been 19 peer-reviewed. 20 Q. I'm asking you -- I'm asking 21 you whether they identified -- 22 MS. MILLER: You just 23 interrupted her. 24 MR. TISI: Okay. I -- there</p>	<p>1 A. Yes, I do. 2 Q. Okay. And "Although the 3 reasons for this are unclear, the 4 difference could potentially be due to 5 issues related to latency, study power or 6 exposure misclassification," correct? 7 A. You know, that's what he 8 says there. And I think it's really 9 striking that he doesn't talk about what 10 most people talk about in terms of the 11 limitations of the case-control studies. 12 So most people would say well, the reason 13 is, is because there's recall bias. And 14 we do have evidence of how recall bias 15 can affect these results from 16 Schildkraut. And so -- and so there it 17 can be kicked around -- 18 Q. There's no question -- 19 there's no question pending. 20 A. Well, you asked me -- 21 Q. I didn't ask you. I asked 22 you whether I read that right. 23 MS. MILLER: Please stop 24 interrupting her.</p>

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<p>1 MR. TISI: I asked you --</p> <p>2 MS. MILLER: She wants to</p> <p>3 give full, accurate answers.</p> <p>4 MR. TISI: But there was no</p> <p>5 question pending.</p> <p>6 MS. MILLER: And you're</p> <p>7 trying to stonewall her.</p> <p>8 MR. TISI: No, she's trying</p> <p>9 to stonewall me.</p> <p>10 BY MR. TISI:</p> <p>11 Q. I'm asking you this. I said</p> <p>12 their reason they identify three reasons</p> <p>13 why there could be a difference between</p> <p>14 the case-control and the cohort studies,</p> <p>15 did they not? And the answer is either a</p> <p>16 yes or no.</p> <p>17 MS. MILLER: Sometimes in</p> <p>18 life an answer isn't yes or no.</p> <p>19 And if the witness feels like she</p> <p>20 needs to give a complete answer,</p> <p>21 please allow her to give a</p> <p>22 complete answer.</p> <p>23 BY MR. TISI:</p> <p>24 Q. Doctor, did I read the</p>	<p>1 addressed in this paper?</p> <p>2 A. I don't know.</p> <p>3 Q. Okay.</p> <p>4 A. And let me just point --</p> <p>5 Q. So now, let's talk about the</p> <p>6 cohort studies, which is what we were</p> <p>7 talking about.</p> <p>8 MS. MILLER: She was in the</p> <p>9 middle of a sentence.</p> <p>10 BY MR. TISI:</p> <p>11 Q. The next paragraph talks</p> <p>12 about latency. It says, "Although cohort</p> <p>13 designs are efficient in examining</p> <p>14 diseases with long latency periods, it is</p> <p>15 essential that the period between talc</p> <p>16 exposures and cancer's diagnosis be</p> <p>17 specific" -- "sufficiently long.</p> <p>18 Gonzales suggested that the latency</p> <p>19 period for ovarian cancer is between 15</p> <p>20 and 20 years.</p> <p>21 "In the cohort studies</p> <p>22 included in this review, Houghton</p> <p>23 reported a mean follow-up of 12.4 years</p> <p>24 while Gates followed a cohort of women</p>
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<p>1 following statement correct:</p> <p>2 "Although the reasons for</p> <p>3 this are unclear, the difference could</p> <p>4 potentially be due to issues related to</p> <p>5 latency, study power, or study</p> <p>6 misclassification."</p> <p>7 A. You read that sentence</p> <p>8 correct. But you were saying that --</p> <p>9 that there are experts outside of</p> <p>10 litigation that have the same objections</p> <p>11 as do the plaintiffs' experts. And so I</p> <p>12 was -- and you're citing this.</p> <p>13 Q. Okay.</p> <p>14 A. And I'm trying to be</p> <p>15 completely, you know, truthful. And I'm</p> <p>16 saying this is surprising to me, because</p> <p>17 first of all, it hasn't been put through</p> <p>18 peer review. So I don't know if this</p> <p>19 will stand. The reviewers may say --</p> <p>20 well, you can say this the other way,</p> <p>21 which most people would, is the issue is,</p> <p>22 is that the case-control studies have</p> <p>23 recall bias and selection bias.</p> <p>24 Q. Have those not been</p>	<p>1 for 24 years. Gertig and Gonzales</p> <p>2 noticed that" -- "noted that one of their</p> <p>3 studies' main limitations one was the</p> <p>4 relatively short follow-up period that</p> <p>5 may not accurately detect a potential</p> <p>6 association between talc exposure and</p> <p>7 ovarian cancer."</p> <p>8 Do you see that?</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: I do see that.</p> <p>11 BY MR. TISI:</p> <p>12 Q. Okay. And that is the very</p> <p>13 same thing that the plaintiffs' experts</p> <p>14 identify, correct?</p> <p>15 MS. MILLER: Objection.</p> <p>16 BY MR. TISI:</p> <p>17 Q. You disagree with it, but</p> <p>18 they identified it?</p> <p>19 MS. MILLER: Objection.</p> <p>20 THE WITNESS: And I'm saying</p> <p>21 that the methodology and -- and</p> <p>22 sort of what's being stated here</p> <p>23 is -- is not a true representation</p> <p>24 of what's going on.</p>

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<p>1 BY MR. TISI: 2 Q. Okay. So they're wrong? 3 MS. MILLER: Objection. 4 THE WITNESS: I'm saying 5 that I -- I think that the 6 methodology applied has not -- has 7 some flaws in it. 8 BY MR. TISI: 9 Q. Okay. So the methodology of 10 these folks outside of litigation are 11 wrong -- 12 A. But these -- 13 Q. -- but yours is right? 14 A. Sorry. 15 Q. Correct? 16 MS. MILLER: Objection. 17 THE WITNESS: I'm saying 18 that I followed the general 19 principles of evaluating causation 20 on the basis of epidemiology good 21 practice. 22 And this has not even been 23 peer-reviewed yet, so... 24 BY MR. TISI:</p>	<p>1 something outside of litigation that 2 hasn't been published to say, look, this 3 is in support of our experts' opinion. 4 So I don't know how that has much weight. 5 Q. The next statement is -- 6 deals with the power issue. In addition 7 cohort studies included -- may have 8 underpowered -- may have been 9 underpowered to detect an odds ratio of 10 1.3 from the case-control studies. This 11 was noted by Narod who suggested a cohort 12 of at least 200,000 women would be needed 13 to reach statistical significance if the 14 true odds ratio is 1.3. The cohort 15 studies included in this review included 16 much smaller cohort studies, ranging 17 between 41,000 and 78,000 women. 18 Do you see that? 19 A. I see where it's stated 20 there. 21 MS. MILLER: You didn't read 22 that exactly. 23 MR. TISI: I didn't read it 24 exactly. You're right.</p>
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<p>1 Q. So the next -- nor has your 2 report, right? 3 MS. MILLER: Objection. 4 BY MR. TISI: 5 Q. Your report hasn't been 6 peer-reviewed, right? 7 MS. MILLER: Objection. 8 THE WITNESS: So I'm not 9 using anything outside of 10 litigation that hasn't been 11 peer-reviewed to say, look, you 12 know, this -- 13 BY MR. TISI: 14 Q. But your -- 15 A. -- is in support of that. 16 And so that's -- 17 Q. But your report -- 18 A. -- what I'm saying. 19 Q. -- has not been 20 peer-reviewed, correct? 21 A. But that wasn't the relevant 22 thing. 23 Q. Okay. 24 A. You were pointing to</p>	<p>1 MS. MILLER: No, you didn't. 2 BY MR. TISI: 3 Q. My question is -- 4 MS. MILLER: So -- 5 BY MR. TISI: 6 Q. -- were any -- were any of 7 the cohort studies above 80,000 women? 8 A. I'm saying that if you look 9 at the meta-analyses of the cohort 10 studies, there -- it meets, as I said in 11 my report, meets the 200,000, and there 12 is sufficient power there. And The 13 meta-analyses of the cohort studies did 14 not find a statistically significant 15 result. 16 Q. Where was the meta-analysis 17 for the cohort studies? Where was that? 18 A. Oh, let's look at -- I think 19 Berge has meta-analysis of the cohort. 20 Penninkilampi also has a meta-analysis. 21 Those are the two most recent ones. And 22 those are published. 23 Q. The next -- the next thing 24 deals with the misclassification bias.</p>

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<p>1 MR. TISI: God bless you.</p> <p>2 BY MR. TISI:</p> <p>3 Q. On the next page, it says,</p> <p>4 Finally, in cohort studies talc exposure</p> <p>5 was assessed at cohort entry and was used</p> <p>6 to measure -- as a measure of chronic</p> <p>7 talc use during follow-up.</p> <p>8 It is possible women who</p> <p>9 were not exposed to perineal talc at the</p> <p>10 time of cohort entry began using talc</p> <p>11 later time and vice versa, possibly</p> <p>12 introducing nondifferential</p> <p>13 misclassification of exposure, which</p> <p>14 could have biased the risk estimate</p> <p>15 towards the null value of unity.</p> <p>16 MS. MILLER: I just want to</p> <p>17 say object. That was paraphrased.</p> <p>18 It wasn't read exactly.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Do you read that?</p> <p>21 A. I see where you're reading</p> <p>22 from.</p> <p>23 Q. And that's the same</p> <p>24 misclassification bias that Dr. Rothman</p>	<p>1 sort of take a deeper dive and see if</p> <p>2 there's any evidence for or against that.</p> <p>3 Q. Let's talk about strength of</p> <p>4 association.</p> <p>5 You -- I'm going to do this</p> <p>6 pretty quickly I think. On Page 22 of</p> <p>7 your report you talk about that, correct?</p> <p>8 A. I have a section that says</p> <p>9 strength of association.</p> <p>10 Q. And the first two sentences,</p> <p>11 you say, "The criterion does not have a</p> <p>12 hard threshold. There is no cut-off</p> <p>13 value for the magnitude of an association</p> <p>14 between an exposure required for a</p> <p>15 relationship to be causal."</p> <p>16 And you agree with that,</p> <p>17 correct?</p> <p>18 A. There's no hard threshold.</p> <p>19 I mean, there is no hard number that, you</p> <p>20 know, people would say, oh, it's 1.31.</p> <p>21 No, it's 1.32.</p> <p>22 Q. Okay. On Page 22, again,</p> <p>23 you say, "Most epidemiologists regard the</p> <p>24 relative risk odds ratio or risk ratios</p>
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<p>1 mentioned and plaintiffs' experts also --</p> <p>2 experts also mentioned as well.</p> <p>3 A. Yeah. And that's just a</p> <p>4 statement there, but it doesn't go into</p> <p>5 sort of how this applies to talc in</p> <p>6 general. It's just a general statement.</p> <p>7 So for instance, it doesn't</p> <p>8 acknowledge that most women begin talc</p> <p>9 use in their early adulthood. It doesn't</p> <p>10 acknowledge that -- so that means that</p> <p>11 most women by the time they're 55,</p> <p>12 probably wouldn't start using talc at</p> <p>13 that point.</p> <p>14 And even if they did, there</p> <p>15 probably wouldn't be sufficient follow-up</p> <p>16 time at that point for ovarian cancer to</p> <p>17 develop.</p> <p>18 So these are much more</p> <p>19 subtle than just sort of stating a</p> <p>20 platitude that, oh, yeah, this is a thing</p> <p>21 you have to look out for in cohort</p> <p>22 studies and, therefore, it's true.</p> <p>23 It is something that you</p> <p>24 have to look out for. But you have to</p>	<p>1 are less than 1.5 to be weak</p> <p>2 relationships."</p> <p>3 Do you see that?</p> <p>4 A. Yes. And I have citations</p> <p>5 there.</p> <p>6 Q. Okay. And then you go on to</p> <p>7 say, "Although there are instances where</p> <p>8 ratios under 1.5 are established to be</p> <p>9 causal based upon observational data,</p> <p>10 there are more instances where they are</p> <p>11 spurious due to confounding or bias."</p> <p>12 Do you see that?</p> <p>13 A. Yep. With the citation.</p> <p>14 Q. Okay. That citation is to</p> <p>15 an article by Taubes?</p> <p>16 A. Mm-hmm.</p> <p>17 Q. Okay. Who is Gary Taubes?</p> <p>18 A. I don't know offhand who he</p> <p>19 is.</p> <p>20 Q. Gary Taubes, is he a doctor?</p> <p>21 A. I -- I don't know offhand.</p> <p>22 If I could see the article. I could see</p> <p>23 if he has a Ph.D. or M.D. behind his</p> <p>24 name.</p>

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<p style="text-align: right;">Page 390</p> <p>1 MR. TISI: Exhibit 30, 2 please. 3 MS. MILLER: So that would 4 be 23. 5 MR. SOILEAU: Yes, that 6 would be 23. 7 MS. MILLER: I can't figure 8 out your code. But you're always 9 off by a always a different 10 number. 11 MR. TISI: Yes, it is, 12 because I'm off my -- 13 MS. MILLER: It's not like I 14 can even add or subtract. 15 (Document marked for 16 identification as Exhibit 17 Ballman-23.) 18 BY MR. TISI: 19 Q. I don't have the whole 20 thing. But I'm going to give you mine. 21 This is an article by Dr. Taubes. And it 22 has my highlighting on it, which of 23 course I will be glad to substitute one. 24 MS. SHARKO: We don't mind</p>	<p style="text-align: right;">Page 392</p> <p>1 really well respected journal. 2 Q. Do you know, Doctor, that 3 Taubes is a journalist and not a doctor? 4 A. Oh, I did not realize that. 5 But he's quoting many individuals in here 6 who are famous epidemiologists, Norman 7 Breslow. 8 Q. Doctor, do you see a nice, 9 big picture of -- 10 A. I see Ken Rothman in there. 11 Q. Yeah. 12 A. Who you say is -- so he -- 13 he may be reporting. But it's -- Sander 14 Greenland. 15 Q. That's the other guy who, if 16 you look at the book there, they both 17 co-authored the book on epidemiology? 18 A. Right. 19 Q. All right. And first of 20 all, is this a peer-reviewed article? 21 A. Since it says "Special news 22 report," I don't know if it was 23 peer-reviewed or not. 24 Q. Did you look and see whether</p>
<p style="text-align: right;">Page 391</p> <p>1 your highlighting. 2 MR. TISI: That's okay. I'm 3 happy to have you show it to the 4 jury. 5 MS. MILLER: There's no jury 6 here. This is a Daubert 7 proceeding. We've established 8 that like 16 times. So I don't 9 know which jury you're talking 10 about. 11 MS. SHARKO: There's never 12 going to be a jury. We're going 13 to be done after Daubert. 14 MR. TISI: There have been 15 plenty of juries. They've all 16 said the same thing. 17 BY MR. TISI: 18 Q. Is that the article that 19 you've referred to? 20 A. Yes, it is. 21 Q. Okay. Can you tell me 22 whether Dr. Taubes -- first of all, it's 23 a news article, isn't it? 24 A. In -- in Science, which is a</p>	<p style="text-align: right;">Page 393</p> <p>1 or not the people who were quoted in this 2 news article, first of all, do you 3 typically cite news articles in your 4 published -- published papers? 5 MS. MILLER: Objection. 6 THE WITNESS: Well, if they 7 interview epidemiologists -- so 8 the epidemiologist interviewed by 9 Science, so I believe that 10 journalist would sort of report 11 correctly what the epidemiologist 12 said that they interviewed. 13 BY MR. TISI: 14 Q. So you don't -- you don't 15 buy fake news, huh? 16 MS. MILLER: Objection. 17 BY MR. TISI: 18 Q. Let me ask you this, Doctor. 19 MS. MILLER: Was that a 20 question that you actually want 21 her -- 22 MR. TISI: Yeah. I withdraw 23 it. I was making a joke, Counsel. 24 MS. MILLER: It's hard to</p>

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<p>1 tell.</p> <p>2 BY MR. TISI:</p> <p>3 Q. Did you see -- did you see</p> <p>4 whether or not the people who were quoted</p> <p>5 wrote a rebuttal to this report?</p> <p>6 A. No, I did not look.</p> <p>7 (Document marked for</p> <p>8 identification as Exhibit</p> <p>9 Ballman-24.)</p> <p>10 BY MR. TISI:</p> <p>11 Q. In the same article, and you</p> <p>12 use the same rigor in doing -- in</p> <p>13 drafting your report that you would do in</p> <p>14 any publication, right?</p> <p>15 MS. MILLER: Objection.</p> <p>16 BY MR. TISI:</p> <p>17 Q. In drafting your expert</p> <p>18 report, you use the same scientific rigor</p> <p>19 that would you use in every publication</p> <p>20 that you -- that you'd use?</p> <p>21 MS. MILLER: Objection.</p> <p>22 THE WITNESS: I applied</p> <p>23 scientific rigor in doing my</p> <p>24 analyses and writing my report.</p>	<p>1 support your -- your statement, yes.</p> <p>2 MS. MILLER: Objection.</p> <p>3 That's --</p> <p>4 BY MR. TISI:</p> <p>5 Q. The next sentence, he says,</p> <p>6 A problem does -- A problem does not</p> <p>7 exist with general medical reports about</p> <p>8 single scientific studies.</p> <p>9 Correct?</p> <p>10 MS. MILLER: Objection.</p> <p>11 MR. LOCKE: Objection. You</p> <p>12 added a "not".</p> <p>13 BY MR. TISI:</p> <p>14 Q. "A problem does exist with</p> <p>15 general media reports about single</p> <p>16 scientific studies."</p> <p>17 Correct?</p> <p>18 A. Yes, that's what it says</p> <p>19 there.</p> <p>20 Q. And most of the examples</p> <p>21 that are cited in the Taubes articles had</p> <p>22 one observational study, correct?</p> <p>23 A. Yeah. That might be the</p> <p>24 case.</p>
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<p>1 BY MR. TISI:</p> <p>2 Q. So in the same journal of</p> <p>3 Science, Drs. -- if you look at the next</p> <p>4 page, Drs. Willett, Greenland, MacMahon</p> <p>5 Rothman, Thomas, Thun and Weiss wrote a</p> <p>6 letter.</p> <p>7 Do you see that?</p> <p>8 A. Yes, I see that.</p> <p>9 Q. Okay. And the first</p> <p>10 sentence says, "In the special news</p> <p>11 report, "Epidemiology Faces Its Limits,"</p> <p>12 Gary Taubes assembles a series of</p> <p>13 quotations from ourselves and others</p> <p>14 about potential methodologic pitfalls in</p> <p>15 epidemiologic studies that might leave</p> <p>16 readers with the misimpression that</p> <p>17 evidence-based epidemiologic findings are</p> <p>18 not usually credible."</p> <p>19 Did I read that right?</p> <p>20 A. Yeah, you read that right.</p> <p>21 Does -- are we talking about -- is this</p> <p>22 all in relation to threshold?</p> <p>23 Q. This is all in relationship</p> <p>24 to the study that you relied on to</p>	<p>1 Q. Okay. Now, talc has, we</p> <p>2 established earlier, over 30, correct?</p> <p>3 A. Well, again, it depends upon</p> <p>4 how you measure studies. I don't know if</p> <p>5 they are 30 independent with different</p> <p>6 datasets.</p> <p>7 Q. Certainly over one?</p> <p>8 A. That's correct.</p> <p>9 Q. Okay. It says, "Taubes</p> <p>10 seems to perpetuate this confusion by</p> <p>11 listing several media reports of</p> <p>12 published findings and telling the</p> <p>13 reader, "You should be the judge."</p> <p>14 Do you see that?</p> <p>15 A. I see where you're reading</p> <p>16 from.</p> <p>17 Q. Okay. It goes on to say,</p> <p>18 "In any scientific field, findings of</p> <p>19 individual studies are not usually</p> <p>20 considered seriously until confirmed by</p> <p>21 others. Also, in epidemiology, as in</p> <p>22 another scientific fields, more powerful</p> <p>23 studies need to be conducted to evaluate</p> <p>24 smaller fixed."</p>

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<p style="text-align: right;">Page 398</p> <p>1 Do you see that?</p> <p>2 MR. LOCKE: Objection.</p> <p>3 THE WITNESS: Yep.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Okay. So you cited the</p> <p>6 Taubes article but you didn't really</p> <p>7 consider the quotations, the</p> <p>8 epidemiologist who thought differently,</p> <p>9 correct?</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: But I think</p> <p>12 there are other quotations, such</p> <p>13 as, "Often doing so will require</p> <p>14 large and long-term prospective</p> <p>15 studies."</p> <p>16 And it also states that,</p> <p>17 "Taubes writes that, I have</p> <p>18 expressed the view that a fourfold</p> <p>19 risk should be taken seriously.</p> <p>20 This is correct, but only when the</p> <p>21 finding stands in the biological</p> <p>22 vacuum" --</p> <p>23 BY MR. TISI:</p> <p>24 Q. Right.</p>	<p style="text-align: right;">Page 400</p> <p>1 Cancer Institute is?</p> <p>2 A. You mean what is it?</p> <p>3 Q. Yes.</p> <p>4 A. I thought you said who. Is</p> <p>5 it who or what?</p> <p>6 Q. What is the National Cancer</p> <p>7 Institute?</p> <p>8 A. So it's -- it's a government</p> <p>9 agency that funds cancer research.</p> <p>10 Q. Okay. Would it surprise you</p> <p>11 that the National Cancer Institute</p> <p>12 characterized risks as low as 1.2 as a</p> <p>13 moderate risk and not a weak risk?</p> <p>14 MR. LOCKE: Objection.</p> <p>15 THE WITNESS: Can I see what</p> <p>16 you're citing that from, please?</p> <p>17 MR. TISI: Sure.</p> <p>18 BY MR. TISI:</p> <p>19 Q. National Cancer Institute,</p> <p>20 PDQ on the NI -- from "Ovarian Fallopian</p> <p>21 Tube and Primary Peritoneal Cancer:</p> <p>22 Peritoneal Cancer Prevention."</p> <p>23 (Document marked for</p> <p>24 identification as Exhibit</p>
<p style="text-align: right;">Page 399</p> <p>1 A. -- "and has no" -- "or no</p> <p>2 biomedical credibility."</p> <p>3 Q. Okay.</p> <p>4 A. "We all take seriously small</p> <p>5 relative risk when there are credible</p> <p>6 hypothesis in the background."</p> <p>7 Q. And you don't think the</p> <p>8 hypothesis that talc could cause ovarian</p> <p>9 cancer is credible?</p> <p>10 A. After doing my complete</p> <p>11 scientific review, I -- I again come to</p> <p>12 the conclusion that there's no evidence</p> <p>13 of a causal relationship between</p> <p>14 peritoneal talcum powder exposure and</p> <p>15 ovarian cancer.</p> <p>16 Q. Okay. You mentioned that</p> <p>17 you think that the -- most</p> <p>18 epidemiologists would categorize the</p> <p>19 risks seen in these studies as weak?</p> <p>20 A. I -- yes.</p> <p>21 Q. Okay. Who is the National</p> <p>22 Cancer Institute?</p> <p>23 A. What is it?</p> <p>24 Q. Do you know who the National</p>	<p style="text-align: right;">Page 401</p> <p>1 Ballman-25.)</p> <p>2 BY MR. TISI:</p> <p>3 Q. Do you see that?</p> <p>4 A. Yes, I see that. That's the</p> <p>5 title of the article. Yes.</p> <p>6 Q. And if you go to Page 3. It</p> <p>7 identifies factors with adequate evidence</p> <p>8 of increased risk of ovarian, fallopian</p> <p>9 tube and primary peritoneal cancer.</p> <p>10 Do you see that?</p> <p>11 A. Yes, I do.</p> <p>12 Q. Okay. And it talks about</p> <p>13 for each one of them, the magnitude of</p> <p>14 the effect?</p> <p>15 A. Yes, I see that.</p> <p>16 Q. Okay. The magnitude of</p> <p>17 effect for endometriosis is modest with</p> <p>18 an observed relative risk rate of 1.8 to</p> <p>19 2.4?</p> <p>20 A. Yes.</p> <p>21 Q. Magnitude of the effect for</p> <p>22 hormone replacement therapy is modest</p> <p>23 with a relative risk of 1.2 to 1.8?</p> <p>24 A. Yes.</p>

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<p style="text-align: right;">Page 402</p> <p>1 Q. And obesity and height talks 2 about, "Based on fair evidence, obesity 3 and height are associated with a modest 4 increase of ovarian cancer," which they 5 describe down below as a 1.1. 6 A. Yes. I see that. 7 MS. MILLER: Can you -- 8 BY MR. TISI: 9 Q. Are there -- so would you -- 10 would you agree with me that at least in 11 this document, that there are people who 12 define magnitude of risk of 1.1 to 1.2 as 13 a modest risk? 14 MS. MILLER: Objection. Are 15 we talking about relative risks? 16 Or are we talking -- 17 MR. TISI: You can clarify, 18 Counsel. She's looking at it. 19 MS. MILLER: That's an 20 objectionable question. 21 MR. TISI: Of course. Every 22 one of my questions is. 23 MS. SHARKO: Exactly. 24 MS. MILLER: Fix that.</p>	<p style="text-align: right;">Page 404</p> <p>1 don't think talc is listed here. 2 Q. I understand. Counsel -- 3 counsel can ask you this question. This 4 is not your opportunity to pontificate. 5 MR. LOCKE: Objection. 6 MS. MILLER: Objection. 7 BY MR. TISI: 8 Q. Let's talk about consistency 9 and statistical significance now, because 10 this is a big part of your report. 11 Please pull out Exhibit 6, 12 which is the Bradford Hill article. 13 A. Yes, I have. 14 Q. On Page 8 it talks about 15 consistency. It says, "Next to my list." 16 A. Yes. 17 Q. Okay. It does not say 18 different designs, does it? Can you read 19 it for the record, please? 20 A. Yes. It says, "Has it been 21 repeatedly observed by different persons 22 in different places, circumstances, and 23 times?" 24 Q. Okay. It doesn't talk about</p>
<p style="text-align: right;">Page 403</p> <p>1 THE WITNESS: So this has 2 nothing to do with -- 3 MS. MILLER: You have the 4 power to change that. 5 MR. TISI: Every one of my 6 questions is. You've made that 7 clear. 8 THE WITNESS: This has 9 nothing to do with trying to 10 identify what the strength of an 11 association is within the context 12 of a Bradford Hill. 13 BY MR. TISI: 14 Q. So is the Bradford -- 15 A. This is more, I think, for 16 lay people. I mean, it says, "Who's at 17 risk?" I don't think this is for 18 scientists. 19 And so, you know, so I don't 20 know what their reference basis is. And 21 I note that -- 22 Q. I have -- no question is 23 pending. 24 A. Let me go through, but I</p>	<p style="text-align: right;">Page 405</p> <p>1 study design, does it? 2 A. I don't know. Circumstances 3 could fall under -- I mean, study design 4 could fall under circumstances. 5 Q. It doesn't say anything 6 about statistical significance, does it? 7 A. You know, I read -- where 8 did I read -- 9 So it's going to take me a 10 while to go through where he talks 11 about -- yeah, so the lesson here is 12 that, "Broadly the same answer has been 13 reached in quite a wide variety of 14 situations and techniques." 15 So I would consider study 16 design a technique. In other words, it's 17 not due to some constant error or fallacy 18 that permeates every inquiry. 19 Q. Okay. So now the next thing 20 if I go to Page 17 of your report under 21 consistency, the second sentence. 22 A. Under consistency. 23 Q. Right. It says -- I'll read 24 it into the record. "Results across</p>

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<p>1 studies are consistent if the risk ratios 2 are numerically close to one another and 3 the results are statistically significant 4 in most studies." 5 A. Yes. 6 Q. Let's take each part. 7 Numerically close to one another. First 8 of all, there's no citation to that 9 whatsoever, is there? 10 A. Again, I mean, it's like 11 what does consistency mean. Well, I 12 mean, it means that you have numbers that 13 are close to each other. A number 14 wouldn't be consistent if one is one and 15 another is 100. I think that's common 16 sense. 17 Q. Okay. Well -- okay. 18 A. And as well as, you know, 19 results are statistically significant in 20 most studies. Again, I think that's how 21 most people -- most epidemiologists would 22 interpret consistency. 23 Q. Well, on Page 26 of the 24 report, if you go there, you criticize</p>	<p>1 asking you one question at a time, 2 Doctor. 3 A. I don't think it's a yes or 4 no answer. 5 Q. Are you not criticizing 6 them -- "Unfortunately, they do not 7 indicate what is meant by relative 8 stability. They did not provide a 9 definition." 10 Do you see that? 11 A. I did not say that they did 12 not provide a cross -- 13 Q. You say, "Unfortunately, 14 they do not indicate what is meant by 15 relative stability." 16 A. Right. I did not say 17 definition. 18 Q. Okay. Do you indicate what 19 you mean by numerically close to one 20 another -- 21 A. So -- 22 Q. -- on Page 17? 23 MS. MILLER: Objection. 24 THE WITNESS: I -- I --</p>
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<p>1 the plaintiffs' experts in another 2 context. You say, "Arguments have been 3 made by plaintiffs' experts that the 4 results are consistent. Some experts 5 emphasize what they see is a relative 6 stability of the estimates across time, 7 diverse population, and across diverse 8 study designs. Unfortunately, they do 9 not indicate what is meant by relative 10 stability." 11 Do you see that? 12 A. I'm sorry, no. I haven't 13 gotten there. 14 Q. It's the last paragraph. 15 A. Yes. I see that. 16 Q. And you're critical of the 17 plaintiffs' experts for in the defining 18 the terms, right? 19 A. But if you go on -- 20 Q. I'm asking you a question. 21 You're critical of plaintiffs' experts 22 for not defining their terms, correct? 23 A. Can I finish? 24 Q. No, I'm asking you -- I'm</p>	<p>1 that's where I was going. It's 2 transfer -- I do have sort of 3 criteria -- where was it, Page 17? 4 So when I apply the 5 criteria, I say how I apply it. 6 And so I'm trying to look for that 7 right now. 8 BY MR. TISI: 9 Q. No, I'm asking you the 10 general principles, Doctor. What is -- 11 how do you define numerically close? 12 What is your definition and your 13 authority for that? 14 A. Common sense. And I'm going 15 to where I applied it, as the plaintiffs 16 did not give this a definition in their 17 sort of how to do consistency and their 18 general setup of consistency, what I'm 19 saying is when they reported their 20 results on consistency, they just make a 21 statement that it's relatively stable, 22 but they don't even give an indication of 23 what they mean by relatively stable. 24 Q. And you don't think the --</p>

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<p style="text-align: right;">Page 410</p> <p>1 A. So in my --</p> <p>2 MS. MILLER: She's still</p> <p>3 talking.</p> <p>4 THE WITNESS: In my general</p> <p>5 setup, I do not indicate. But I</p> <p>6 do when I go through sort of the</p> <p>7 consistency evaluation, I do give</p> <p>8 magnitudes of the ranges that were</p> <p>9 reported in the case-control</p> <p>10 studies that are almost fourfold</p> <p>11 different.</p> <p>12 BY MR. TISI:</p> <p>13 Q. I understand.</p> <p>14 A. Versus -- well, that's</p> <p>15 what -- you asked me about consistency.</p> <p>16 Q. No. But I'm asking you</p> <p>17 where you -- no, but I'm asking --</p> <p>18 A. And that's how I --</p> <p>19 Q. You're not answering my</p> <p>20 question.</p> <p>21 MS. MILLER: Stop talking</p> <p>22 over each other. Let her finish</p> <p>23 her sentence.</p> <p>24 BY MR. TISI:</p>	<p style="text-align: right;">Page 412</p> <p>1 THE WITNESS: -- the</p> <p>2 analysis -- I'm answering.</p> <p>3 BY MR. TISI:</p> <p>4 Q. You are not --</p> <p>5 MS. MILLER: Let her finish</p> <p>6 her sentence.</p> <p>7 BY MR. TISI:</p> <p>8 Q. You are not answering my</p> <p>9 question with all due respect.</p> <p>10 MS. SHARKO: You haven't</p> <p>11 heard her whole answer.</p> <p>12 MR. TISI: This is --</p> <p>13 MS. MILLER: Maybe -- maybe</p> <p>14 she was about to give you the</p> <p>15 answer you wanted.</p> <p>16 MR. TISI: This is --</p> <p>17 MS. MILLER: You have to let</p> <p>18 her finish talking.</p> <p>19 BY MR. TISI:</p> <p>20 Q. This is -- you provide --</p> <p>21 MS. MILLER: You don't let</p> <p>22 me talk either.</p> <p>23 BY MR. TISI:</p> <p>24 Q. You provide a statement,</p>
<p style="text-align: right;">Page 411</p> <p>1 Q. You are really not answering</p> <p>2 my question.</p> <p>3 Doctor, with all due</p> <p>4 respect, and I -- because I think it's</p> <p>5 important here. I want to know what your</p> <p>6 definition is of numerically close, and I</p> <p>7 want to know where you get it from.</p> <p>8 A. So I think this is a bit</p> <p>9 unfair. You're asking me for a</p> <p>10 definition of numerically close. And</p> <p>11 when I just sort of give a general</p> <p>12 gestalt of what's meant by consistency.</p> <p>13 And then you're saying but</p> <p>14 you criticize the other plaintiffs'</p> <p>15 experts because they don't say what</p> <p>16 relatively stable is. And their</p> <p>17 statements are in terms of when they</p> <p>18 looked at consistency, not a definition</p> <p>19 of consistency.</p> <p>20 So I'm saying let's look and</p> <p>21 I'll show you why I say they're not</p> <p>22 consistent. And when I invoke --</p> <p>23 Q. But you're not answering.</p> <p>24 MS. MILLER: Let her finish.</p>	<p style="text-align: right;">Page 413</p> <p>1 okay, here about consistency. This is in</p> <p>2 your general section, 5.1.2, correct?</p> <p>3 Without regard to talc.</p> <p>4 A. I -- I say -- I provide a</p> <p>5 general statement there.</p> <p>6 Q. Okay. And your general</p> <p>7 statement is that numerically close --</p> <p>8 A. Yes.</p> <p>9 Q. Okay. You use numerically</p> <p>10 close. And I want to know where -- other</p> <p>11 than you said common sense and gestalt,</p> <p>12 okay, those are your two things, kind of</p> <p>13 like the sniff test that you used in</p> <p>14 Viagra, right?</p> <p>15 MR. LOCKE: Objection.</p> <p>16 BY MR. TISI:</p> <p>17 Q. I want to know where your --</p> <p>18 where your --</p> <p>19 MS. MILLER: He wasn't done</p> <p>20 with the question. I was going to</p> <p>21 object. Don't worry.</p> <p>22 BY MR. TISI:</p> <p>23 Q. Okay. Then let me back up.</p> <p>24 You remember the sniff test that you used</p>

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<p>1 in Viagra, right?</p> <p>2 MS. MILLER: Objection.</p> <p>3 THE WITNESS: I don't</p> <p>4 remember exactly how I used it. I</p> <p>5 do remember using those terms.</p> <p>6 BY MR. TISI:</p> <p>7 Q. Right. So this is the</p> <p>8 gestalt test or the common sense test</p> <p>9 that you used.</p> <p>10 MS. MILLER: Objection.</p> <p>11 BY MR. TISI:</p> <p>12 Q. I want to know exactly where</p> <p>13 you get your cut-off for what is</p> <p>14 numerically close for the consistency</p> <p>15 prong of Bradford Hill?</p> <p>16 MR. LOCKE: Objection.</p> <p>17 THE WITNESS: You know what,</p> <p>18 again, it all depends upon the</p> <p>19 situation. And that's why there's</p> <p>20 no solid number within the</p> <p>21 definition for the general thing.</p> <p>22 You also then brought up --</p> <p>23 and that's what I'm trying to get</p> <p>24 the whole truth out there, is I</p>	<p>1 conclusion, versus the plaintiffs'</p> <p>2 experts, which just say they're</p> <p>3 relatively stable.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Okay. Let me do the next</p> <p>6 one. Last paragraph in the consistency</p> <p>7 section, last -- I'm going to read it</p> <p>8 into the record. It's the first</p> <p>9 paragraph.</p> <p>10 "However" --</p> <p>11 MS. MILLER: You said last</p> <p>12 paragraph. Then you said first</p> <p>13 paragraph.</p> <p>14 BY MR. TISI:</p> <p>15 Q. First paragraph, last couple</p> <p>16 sentences.</p> <p>17 Tell me where you are. Are</p> <p>18 you with me, Doctor? Right here.</p> <p>19 Consistency. Page 17.</p> <p>20 A. No, I was on 24. Yes.</p> <p>21 Q. Okay. You say -- I'll read</p> <p>22 it into the record. "However, if</p> <p>23 adequately powered studies do not achieve</p> <p>24 statistical significance, this is</p>
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<p>1 criticize the plaintiffs' experts</p> <p>2 by saying relatively stable</p> <p>3 without giving any sort of</p> <p>4 indication.</p> <p>5 But their relatively stable</p> <p>6 was just in their conclusion that</p> <p>7 they're consistent, whereas when I</p> <p>8 look at the consistency analyses,</p> <p>9 I give more numbers and ranges as</p> <p>10 to why I believe those numbers are</p> <p>11 not consistent.</p> <p>12 BY MR. TISI:</p> <p>13 Q. Right. But that's your</p> <p>14 opinion. You don't give any basis for</p> <p>15 it. You don't give any citation. You</p> <p>16 don't give any published peer-reviewed</p> <p>17 literature which would -- against which</p> <p>18 we could measure your opinion, do you?</p> <p>19 MS. MILLER: Objection.</p> <p>20 THE WITNESS: There wouldn't</p> <p>21 be any published peer-reviewed</p> <p>22 literature that would say that.</p> <p>23 But I am -- I'm giving my criteria</p> <p>24 and metrics and how I came to my</p>	<p>1 evidence of inconsistency."</p> <p>2 Do you stand by that</p> <p>3 statement, first of all?</p> <p>4 A. However if adequately</p> <p>5 powered studies do not achieve</p> <p>6 statistical significance... Yes.</p> <p>7 Q. Okay. Next thing. "Another</p> <p>8 way an inconsistency can rise is if</p> <p>9 95 percent confidence intervals for the</p> <p>10 risk ratio estimates have no to little</p> <p>11 overlap with one another for adequately</p> <p>12 powered studies. If one study has a</p> <p>13 statistically significant result and the</p> <p>14 other does not, it means that the</p> <p>15 magnitude of the relative risk differs</p> <p>16 considerably, which is an inconsistency</p> <p>17 between the size of the estimated risk.</p> <p>18 Do you see that?</p> <p>19 A. I do see that.</p> <p>20 Q. Okay. Can you tell me</p> <p>21 what -- how you define no to little</p> <p>22 overlap? What's the -- what's the</p> <p>23 criteria for that and where do you get it</p> <p>24 from?</p>

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<p style="text-align: right;">Page 418</p> <p>1 First of all, there's no 2 citation for any of this, is there? 3 MS. MILLER: Objection. 4 First of all, so what is -- 5 MR. TISI: I was -- 6 MS. MILLER: You can't ask a 7 question that way. 8 MR. TISI: Counsel, I said 9 first of all, there is -- 10 MS. MILLER: Is the first 11 question stricken? 12 MR. TISI: Yes. 13 MS. MILLER: Okay. 14 BY MR. TISI: 15 Q. First of all, in the second 16 part of the paragraph you do not provide 17 a single citation, correct? 18 A. I do not provide a citation 19 there. 20 Q. Okay. Secondly -- okay, can 21 you tell me what you mean by no to little 22 overlap? What is the criteria and where 23 do you get it from? 24 A. That's was what I was trying</p>	<p style="text-align: right;">Page 420</p> <p>1 2016 and again just this week have 2 indicated that statistical significance 3 should not even be -- should not even be 4 mentioned when we are talking about 5 analyses like these, true? 6 MR. LOCKE: Objection. 7 MS. MILLER: Objection. 8 THE WITNESS: I have no idea 9 what it's referring to. But let 10 me -- let me sort of explain to 11 you the relationship between 12 statistical significance and 13 confidence intervals. 14 If one has a confidence 15 interval, one can infer whether or 16 not a result is statistically 17 significant at a certain level. 18 So one can sort of infer if 19 the P-value is going to be less 20 than or greater than .05 if you're 21 using a 95 percent confidence 22 interval. 23 So the reason they're saying 24 this, and I tell this people all</p>
<p style="text-align: right;">Page 419</p> <p>1 to answer. I'm trying to see if I have 2 that citation here. And if I don't, I 3 can provide a citation. No, I don't 4 provide a citation there. But in the 5 literature, there are articles that state 6 how much -- in fact, confidence intervals 7 can overlap and the results still are 8 statistically significantly different. 9 Q. In fact, Doctor -- and we're 10 going to talk about this. Aren't you 11 aware that even this week, the American 12 Statistical Association published a 13 whole -- a whole volume of 43 articles 14 with an editorial recommending that they 15 get rid of the issue of statistical 16 significance and look at confidence 17 intervals? 18 A. Well, that's what I'm citing 19 there, that one can look at confidence 20 intervals and see if they overlap or not. 21 Q. Perfect. And we're going to 22 talk about that. Okay? 23 But you do understand that 24 the American Statistical Association in</p>	<p style="text-align: right;">Page 421</p> <p>1 the time when I teach, I never 2 just want to see a P-value, I want 3 the magnitude of the difference. 4 I want to know what is the 5 size of the difference and a 6 confidence interval on that, and I 7 would agree. I don't need the 8 P-value. 9 BY MR. TISI: 10 Q. And -- 11 A. And I could infer 12 statistical significance just based upon 13 the confidence interval. 14 So they are not saying don't 15 worry about statistical significance. 16 They are saying don't place so much 17 emphasis on the P-value itself. 18 Q. But also -- we're going to 19 talk about this for a moment. You would 20 agree that almost all of these studies 21 with a handful of exceptions, regardless 22 of study design, their confidence 23 intervals overlap at 1.2? 24 A. I have no idea.</p>

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<p style="text-align: right;">Page 422</p> <p>1 Q. We'll talk about that.</p> <p>2 MS. MILLER: Do you need a</p> <p>3 break?</p> <p>4 THE WITNESS: No, I'm good.</p> <p>5 BY MR. TISI:</p> <p>6 Q. On Page 26, you say the</p> <p>7 following with respect to the talc</p> <p>8 evidence: "There is clear</p> <p>9 inconsistency" -- Page 26?</p> <p>10 A. Yeah, I'm there. I'm not</p> <p>11 seeing where that statement -- or where</p> <p>12 that --</p> <p>13 Q. The last sentence of the</p> <p>14 paragraph in the middle?</p> <p>15 A. Okay. I'm with you.</p> <p>16 Q. There is clear inconsistency</p> <p>17 between different study types with</p> <p>18 case-control studies yielding a</p> <p>19 statistically significant association</p> <p>20 ranging from 1.26 to 1.35 and cohort</p> <p>21 studies yielding a nonstatistically</p> <p>22 significant association ranging from 1.02</p> <p>23 to 1.06, hence no evidence of a causal</p> <p>24 relationship because the results are</p>	<p style="text-align: right;">Page 424</p> <p>1 expert reports of any of the other</p> <p>2 defense experts in this case?</p> <p>3 A. Other defense experts?</p> <p>4 Q. Have you read Christian</p> <p>5 Merlo's?</p> <p>6 A. Yes, I have.</p> <p>7 Q. Did you have any problems</p> <p>8 with his report?</p> <p>9 A. Problems? What do you mean</p> <p>10 by problems.</p> <p>11 Q. Anything that you thought</p> <p>12 was wrong?</p> <p>13 A. I wasn't evaluating whether</p> <p>14 or not I agree or disagree with his</p> <p>15 report.</p> <p>16 Q. I'm going to show you a</p> <p>17 chart that he put in his report because</p> <p>18 you don't have one in yours. And I will</p> <p>19 stipulate that it is accurate to the</p> <p>20 extent that it is --</p> <p>21 A. Comes from his report?</p> <p>22 Q. I'm going to ask you to</p> <p>23 assume that it comes from his report and</p> <p>24 I'm going to use his numbers.</p>
<p style="text-align: right;">Page 423</p> <p>1 inconsistent."</p> <p>2 Do you say that?</p> <p>3 A. I do.</p> <p>4 Q. Okay. And so you think that</p> <p>5 because these two sets of results are --</p> <p>6 one is statistically significant and one</p> <p>7 is not statistically significant, they</p> <p>8 are inconsistent?</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: I'm saying</p> <p>11 that one set of results is</p> <p>12 establishing an association that's</p> <p>13 statistically significant. And</p> <p>14 I'm saying another one is saying</p> <p>15 there is no association because</p> <p>16 this is no statistical</p> <p>17 significance.</p> <p>18 BY MR. TISI:</p> <p>19 Q. Okay. Now, you didn't put a</p> <p>20 Forest plot of the studies in your</p> <p>21 report, did you?</p> <p>22 A. I believe there is no Forest</p> <p>23 plot.</p> <p>24 Q. Okay. Have you reviewed the</p>	<p style="text-align: right;">Page 425</p> <p>1 MS. MILLER: I'll check my</p> <p>2 laptop to make sure that's true.</p> <p>3 (Document marked for</p> <p>4 identification as Exhibit</p> <p>5 Ballman-26.)</p> <p>6 BY MR. TISI:</p> <p>7 Q. Do you remember seeing this</p> <p>8 chart?</p> <p>9 A. I was expecting a Forest</p> <p>10 plot. Yes, I see this chart here. I've</p> <p>11 seen so many charts that if this comes</p> <p>12 from his study, yes, I believe --</p> <p>13 Q. And I'm using his because</p> <p>14 I'm sure the defense would object to me</p> <p>15 using anything else but their evidence.</p> <p>16 I'm using your evidence, and I'm putting</p> <p>17 it in front of you. Okay?</p> <p>18 MS. MILLER: Objection.</p> <p>19 BY MR. TISI:</p> <p>20 Q. And I'm asking you to assume</p> <p>21 it's true.</p> <p>22 MS. MILLER: If there's a</p> <p>23 statement there, I'm objecting.</p> <p>24 If there's a question there, I'm</p>

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<p style="text-align: right;">Page 426</p> <p>1 objecting. If there's a statement 2 there, I don't know what the point 3 of it was. 4 BY MR. TISI: 5 Q. There are 30 observational 6 studies here. And he identified them as 7 hospital-based case-control, 8 population-based case-controls, pooled 9 case-control studies, and cohort studies, 10 correct? 11 A. Yes, that's -- 12 MR. LOCKE: Objection. 13 Before you answer that question, I 14 don't have a copy of what you're 15 looking at. 16 MR. TISI: Oh, I'm sorry. 17 MS. MILLER: Wait. I'm 18 sorry. Did you just read us a 19 sentence? 20 THE WITNESS: No, he was -- 21 MR. TISI: They're 22 categorized. No, it's not. 23 They're categorized. One, 24 hospital based case-control</p>	<p style="text-align: right;">Page 428</p> <p>1 statistically -- statistical significance 2 issue, you would agree with me for the 3 hospital case-control studies with the 4 exception of the two Hartge papers, all 5 show a risk ratio greater than one? 6 A. The two Hartge pages? 7 Q. Yes. 8 A. Yes. That's what it's 9 showing here. 10 Q. Okay. You would also agree 11 with me that the population based 12 case-control studies, every single one of 13 them, whether they were statistically 14 significant or not, had a risk ratio of 15 greater than one. 16 MS. MILLER: Objection. 17 THE WITNESS: In this chart 18 that is true. 19 BY MR. TISI: 20 Q. Okay. The pooled 21 case-control study, Terry had a risk 22 ratio greater than one? 23 A. That's true. That's what 24 this --</p>
<p style="text-align: right;">Page 427</p> <p>1 studies, population based 2 case-control studies -- 3 MS. MILLER: You talked so 4 fast, I thought you were reading 5 something that I didn't have. 6 I didn't realize you were -- 7 MR. TISI: I am reading it. 8 BY MR. TISI: 9 Q. Okay. There are four 10 categories of studies in this chart, 11 correct? 12 A. Yes, he lists four 13 categories of studies in the chart. 14 Q. And these four categories 15 are -- these studies are studies you 16 recognize, correct? 17 A. Yes. I recognize studies 18 that I reviewed. I don't know if they 19 are all there or if any extra or there. 20 But yes, in general. 21 Q. Okay. Now, would you agree 22 that irrespective of -- and I'm going to 23 put this aside for a minute. I'm going 24 to say it. Irrespective of the</p>	<p style="text-align: right;">Page 429</p> <p>1 Q. As was -- as is Cramer on 2 the next page? 3 A. Yes. 4 Q. And the cohort studies all 5 had risk ratios greater than one with the 6 exception of Gonzalez, correct? 7 A. Yes, that's correct. 8 Q. And would you agree with me, 9 risk ratio, the RR, is the same thing as 10 the point estimate, correct? 11 A. Yeah. Either it's an odds 12 ratio or it's a relative risk. But they 13 are point estimates. 14 Q. And the point estimate, just 15 for anybody going to read this, is the 16 most likely place where the risk resides? 17 A. It's more subtle than that. 18 Q. Okay. But just -- well, how 19 would you describe it? 20 A. I would say that what a 21 confidence interval shows, and this is 22 why people hate statistics, is that -- 23 (Brief telephone 24 interruption.)</p>

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<p style="text-align: right;">Page 430</p> <p>1 MS. SHARKO: That's someone 2 who loves statistics. 3 MR. TISI: Troy Rafferty was 4 calling to you. 5 MS. SHARKO: I'm happy to 6 talk with Troy. 7 THE WITNESS: Sorry. I was 8 trying to concentrate. 9 MS. MILLER: Yeah, that's 10 not fair to Dr. Ballman. Should 11 we -- the banter has confused her. 12 Should we go back and hear the 13 question again. 14 BY MR. TISI: 15 Q. Yeah. My question -- my 16 question is, what is your definition of a 17 point estimate. 18 Actually, let me -- let 19 me -- actually, that was not the 20 question. The question was, the point 21 estimate is the place within the 22 confidence interval that it's most likely 23 to be the true risk? 24 A. No, that's not correct.</p>	<p style="text-align: right;">Page 432</p> <p>1 before, Gonzalez, the -- cohort study, 2 and the two Hartge studies, that all of 3 the risk ratios here show a positive risk 4 ratio greater than one? 5 MS. MILLER: Objection. 6 THE WITNESS: As we 7 mentioned, most of the numbers 8 here are bigger than one. 9 BY MR. TISI: 10 Q. Okay. And that's what we 11 call a positive association, a positive 12 risk ratio? 13 MS. MILLER: Objection. 14 THE WITNESS: Well, I think 15 that -- 16 BY MR. TISI: 17 Q. Putting statistical 18 significance aside for a moment. I'll 19 talk about statistical significance. 20 A. Yeah, but I think it's 21 important. I think one would not say 22 there's a positive association if it's 23 not statistically significant. I mean, 24 it depends upon the context in which he</p>
<p style="text-align: right;">Page 431</p> <p>1 Q. Okay. Well, what is it? 2 A. So it's just the point 3 estimate that comes on based on the 4 actual data that you have on hand and 5 that you calculated. And it's for that 6 data. 7 And a confidence interval is 8 the interval such that if you would redo 9 the study with a different random set, 10 selected exactly the same way, many, many 11 times 95 percent of those intervals would 12 contain the real risk ratio. 13 Q. And is the number that is 14 reported, the risk ratio, more likely or 15 less likely than the number that's at the 16 tails? 17 A. I don't know how you would 18 measure that necessarily. Because you 19 have no idea what truth is. So you have 20 no idea within a given confidence 21 interval where the real estimate lies. 22 Q. But you would agree with me 23 that -- that all of these studies with 24 the exceptions that we talked about</p>	<p style="text-align: right;">Page 433</p> <p>1 was saying, so that might be misleading. 2 I mean, you know, a lot of people might 3 say, oh, they said there's a positive 4 association, and they would assume that 5 it was statistically significant. 6 Q. I understand. And we're 7 going to talk about statistical 8 significance in a moment. But I'm asking 9 you, all of these numbers with the 10 exception of the ones that I mentioned, 11 the two Houghton studies and the Gonzalez 12 cohort study, show a positive risk ratio? 13 MS. MILLER: Objection. 14 THE WITNESS: I mean, that's 15 one thing, yes, here in the study. 16 BY MR. TISI: 17 Q. Okay. 18 A. Risk ratios that are -- you 19 know, rated as weak, or no risk -- no 20 significant association. 21 Q. Okay. Now, I'm going to ask 22 you a hypothetical. If every one of 23 these studies was statistically 24 significant instead of some of them yes,</p>

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<p style="text-align: right;">Page 434</p> <p>1 some of them no, would you find 2 consistency? 3 MS. MILLER: Objection. 4 THE WITNESS: If every what? 5 BY MR. TISI: 6 Q. If every one -- 7 A. That that's not -- but 8 that's not the case. 9 Q. I understand. This is a 10 hypothetical. And I'm allowed to ask 11 hypotheticals. 12 If this chart were that 13 every one of these results were 14 statistically significant, would that -- 15 would those be consistent in your 16 opinion? 17 MS. MILLER: Objection. 18 THE WITNESS: Again, I mean, 19 I would have to look at the 20 ranges. They said it's just 21 magnitude. And then even 22 furthermore, you know, the next 23 step then would be consistent 24 what, and consistently biased,</p>	<p style="text-align: right;">Page 436</p> <p>1 that. I'm allowed to ask you 2 hypotheticals. 3 Okay. So my hypothetical is 4 that this chart -- this chart is exactly 5 as it is, except in the right-hand 6 column, there would be -- let's say -- 7 let's call them all weak associations. 8 Let's call them all weak but they would 9 all be statistically significant. 10 If that were to change, 11 would those, in your opinion, be 12 consistent? 13 MS. MILLER: Objection. 14 THE WITNESS: I think it 15 depends. And I think there 16 wouldn't be agreement in terms of 17 what the actual association is, 18 which would be quite weird. And 19 the fact that, you know, in 20 general, the cohort studies have 21 much lower estimates than do the 22 case-control studies. 23 BY MR. TISI: 24 Q. So is your answer they would</p>
<p style="text-align: right;">Page 435</p> <p>1 because these are all population 2 studies, and hence that's probably 3 why -- 4 BY MR. TISI: 5 Q. Well, no. There are cohort 6 studies in there. There's 7 hospital-based. If all of these studies, 8 regardless of design, was statistically 9 significant and the risk ratios were the 10 same, would they be consistent in your 11 opinion? 12 A. You know, again, I would 13 have to see what the actual numbers 14 were -- 15 Q. These are the numbers. 16 A. -- and so forth. 17 Q. These are the numbers. 18 A. But -- yeah, but you're 19 asking me to hypothesize something on 20 numbers that did not yield statistically 21 significant results. 22 Q. I understand. I'm 23 allowed -- I'm allowed to do that. I 24 really -- and your lawyers will tell you</p>	<p style="text-align: right;">Page 437</p> <p>1 be inconsistent? 2 A. I am saying it depends in 3 this hypothetical situation. I mean, I 4 would have to look at it more carefully 5 and do an analysis to see -- 6 Q. Would you -- 7 A. -- because that wasn't the 8 analyses that I did. I did the analyses 9 on -- on these observed results. 10 Q. Okay. Would you agree that 11 most of these risk ratios are between 12 approximately 1.1, some higher, some 13 lower, and 1.5? 14 A. No. There are some that's 15 3.9, I see. 16 Q. Well, so my next point -- 17 A. You know that's for 18 concerning. 2.49. 19 Q. Right. 20 A. I see a .7. I see a .3. 21 Q. I said most of them. Most 22 of -- most of them are in the range of 23 1.1 to 1.5. Not all of them. I 24 wasn't -- I was clear about that.</p>

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<p style="text-align: right;">Page 438</p> <p>1 A. Well, you're right. 2 MS. MILLER: Objection. 3 Wait, is that a question? 4 MR. TISI: Yes. 5 BY MR. TISI: 6 Q. I'm asking you -- 7 MS. MILLER: Or just a 8 statement? That's a statement. 9 BY MR. TISI: 10 Q. I'm asking you, were -- are 11 most -- most of these results are between 12 1.1 and 1.5, true? 13 A. So I would say that the 14 statement you made, however you define 15 most, I'm not quite sure, look like that 16 could be true, yes. 17 MS. MILLER: Is this a good 18 time for a break? 19 MR. TISI: Let me just -- 20 THE WITNESS: Yeah. 21 MS. MILLER: My head is 22 pounding. 23 THE WITNESS: So is mine, 24 actually.</p>	<p style="text-align: right;">Page 440</p> <p>1 THE VIDEOGRAPHER: All 2 right. The time is 3:35 p.m. off 3 the record. 4 (Short break.) 5 THE VIDEOGRAPHER: We are 6 back on the record. The time is 7 3:51 p.m. 8 BY MR. TISI: 9 Q. Doctor, we were talking 10 before the break about role of 11 statistical significance and the issue of 12 consistency. Do you remember that? 13 A. I know that we were talking 14 about consistency and statistical 15 significance, yes. 16 Q. Okay. I'm going to hand you 17 another chapter from Rothman's textbook. 18 I'll have that marked as the 19 next exhibit. 20 MR. SOILEAU: Which will be 21 27. 22 (Document marked for 23 identification as Exhibit 24 Ballman-27.)</p>
<p style="text-align: right;">Page 439</p> <p>1 MS. MILLER: Soon as the 2 statistics started my head started 3 hurting. 4 MR. TISI: Let me just -- 5 let me just finish this, like, one 6 or two sentences, if you don't 7 mind. 8 MS. MILLER: Sure. 9 BY MR. TISI: 10 Q. Now, you said before on Page 11 17 -- on Page 17, "However, adequately 12 powered studies do not achieve 13 statistical significance, that is 14 evidence of inconsistency." 15 A. That is correct. 16 Q. So you are relying on the 17 statistically significant metric as part 18 of your analysis of consistency, true? 19 A. I am, or you could put it 20 another way and say that all of the 21 adequately powered studies would have to 22 have as their lower bound above 1.0. 23 MR. TISI: Okay. That's 24 fine. Let's take a break.</p>	<p style="text-align: right;">Page 441</p> <p>1 BY MR. TISI: 2 Q. Give that to your counsel. 3 Now, there is a section here on 4 consistency in the Bradford Hill 5 criteria, and it starts on Page 25 of 30. 6 Do you see that? 7 A. So causal criteria is on 8 this page, and strength. 9 Q. Correct. That's the section 10 that talks about Bradford Hill. Do you 11 see that? He refers to Bradford Hill, a 12 commonly used set of criteria was based 13 on a list of considerations or viewpoints 14 composed by Sir Bradford Hill. That's 15 the second paragraph there. 16 Do you see that? 17 A. Yes, I do. 18 Q. Okay. And he then goes 19 through the nine aspects. I'm just 20 orienting you here. There's a section on 21 consistency. 22 Do you see that? 23 A. Yes. 24 Q. Okay. Feel free to look at</p>

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<p style="text-align: right;">Page 442</p> <p>1 it if you want. It's only two 2 paragraphs. But I'm going to focus on 3 the second paragraph. First of all, 4 consistency is not a necessary criteria 5 according to Dr. Rothman, right? 6 MS. MILLER: Have you read 7 this? 8 THE WITNESS: No, I'm still 9 reading. Okay, I've read it. 10 BY MR. TISI: 11 Q. Okay. Does he not say, in 12 the second paragraph, "One mistake in 13 implementing the consistency criterion is 14 so common it deserves special attention. 15 It is sometimes claimed that a literature 16 or set of results is inconsistent simply 17 because some results are statistically 18 significant and some are not. 19 "This sort of evaluation is 20 completely fallacious, even if one 21 accepts the use of significance testing 22 methods." 23 Did I read that correctly, 24 first of all?</p>	<p style="text-align: right;">Page 444</p> <p>1 studies for power in the talc litigation? 2 A. I did not. 3 Q. You did not. So you don't 4 know whether they were adequately powered 5 or not, do you? 6 A. I -- I did not go through 7 and do a powered calculation for the 8 studies. 9 Q. So you can't determine 10 whether or not you applied that rule 11 correctly because you don't know whether 12 or not these were adequately powered 13 studies or not, do you? 14 A. I don't know if it was a 15 rule. I'm just saying that this is one 16 aspect of consistency. That's what I 17 said. 18 Q. Okay. So do you agree with 19 Dr. -- Dr. Rothman that just because some 20 studies are not statistically significant 21 and others are, it does not make them 22 inconsistent? 23 A. So what is adequately 24 powered is if one does a meta-analyses of</p>
<p style="text-align: right;">Page 443</p> <p>1 A. That is what it says. 2 Q. Okay. Do you agree with 3 that? 4 A. So it also says that -- 5 Q. I'm asking whether you agree 6 with that statement. Okay. Do you agree 7 with it? 8 A. Well, I do not agree with 9 it. And I'm going to explain why. 10 Q. Okay. 11 A. It goes on to -- well, it 12 says that -- I agree with it in some 13 sense. In the sense that the results -- 14 effect estimates from a set of studies 15 could all be identical even if they -- 16 many were -- many were significant and 17 many were not, the difference in 18 significance arising solely because of 19 differences in the standard error or 20 sizes of the study. 21 And if you recall, I said 22 adequately powered studies, which is what 23 he made this statement here. 24 Q. Did you analyze each of the</p>	<p style="text-align: right;">Page 445</p> <p>1 all the case-control studies and one does 2 a meta-analyses of all the cohort 3 studies. 4 Q. I didn't ask you that 5 question, respectfully. Okay. My 6 question was -- 7 MS. MILLER: Try not to 8 interrupt her. 9 BY MR. TISI: 10 Q. Do you agree -- 11 MS. MILLER: It's so tiring. 12 MR. TISI: No, it is -- 13 listening to her speechify is 14 really disrupting. 15 MS. MILLER: That's the pot 16 calling the kettle black. 17 BY MR. TISI: 18 Q. Do you agree with 19 Dr. Rothman that because some studies are 20 not statistically significant and others 21 are, it does not make them inconsistent? 22 Do you agree with that statement as a 23 general proposition? 24 MR. LOCKE: Objection.</p>

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<p style="text-align: right;">Page 446</p> <p>1 THE WITNESS: It depends.  2 BY MR. TISI:  3 Q. Okay. And it depends upon  4 the power, correct?  5 A. No. It depends upon the  6 situation, as I was trying to explain and  7 you wouldn't let me finish.  8 Q. Okay. Does it depend upon  9 the power of the study to detect an  10 association?  11 A. You mean a statistically  12 significant association?  13 Q. Yes.  14 A. That is what power is about.  15 Q. Correct. Okay. The study,  16 each study has to be powered to find the  17 association, correct, adequately powered?  18 A. No. Just because a study is  19 adequately powered, it could not find an  20 association because there really is no  21 real relationship there.  22 Q. Let's go to Exhibit Number  23 23. Again, this was Dr. Rothman's six  24 misconceptions.</p>	<p style="text-align: right;">Page 448</p> <p>1 A. No. That's not what I'd  2 done. I would like some time please to  3 read the rest of this.  4 Q. Sure.  5 A. He does say, "Focusing on  6 the magnitude" --  7 Q. Just -- I thought you were  8 going to read the whole -- I thought you  9 were going to read the whole thing.  10 Let's read the whole thing and we can  11 talk about it. Thank you.  12 A. Okay.  13 MS. MILLER: It would be  14 really nice if you would not talk  15 over the witness.  16 MR. TISI: It would be  17 really nice if she'd --  18 MS. MILLER: It's especially  19 offensive for the way you are  20 talking to her.  21 MR. TISI: Okay. You know,  22 I find it offensive that a witness  23 would come in here, and I ask her  24 whether or not this pen is red and</p>
<p style="text-align: right;">Page 447</p> <p>1 A. Yes. 20.  2 Q. Exhibit 20. I'm sorry. Go  3 to Misconception Number 6. Can you read  4 what it is?  5 A. Okay.  6 Q. Could you read -- could you  7 read it for the record, Misconception  8 Number 6?  9 A. Oh, read it out loud?  10 Q. Yes.  11 A. Just that piece?  12 Q. Just what the misconception  13 is, and we can talk about what he says.  14 A. Okay. It says,  15 "Misconception 6. Significance testing  16 is useful and important for the  17 interpretation of data."  18 Q. Okay. Is that what -- isn't  19 that what you've done here, is you've  20 looked at, you've looked at which studies  21 are statistically significant and which  22 ones aren't, and you've said that they  23 were inconsistent and, therefore, you did  24 not find inconsistency?</p>	<p style="text-align: right;">Page 449</p> <p>1 she talks about all the reasons  2 why the blue pen down the table is  3 blue. Okay. I find that  4 offensive. That's not the way  5 this works.  6 MR. LOCKE: Objection.  7 MS. SHARKO: That's not what  8 happened. That's not what just  9 happened.  10 MS. MILLER: You just kicked  11 me again. I hope you're not doing  12 that on purpose.  13 MR. TISI: I'm definitely  14 not doing it on purpose. I would  15 not do that. And you kicked me  16 before, and I said nothing about  17 it.  18 MS. MILLER: I don't think  19 my legs are long enough.  20 MR. TISI: Well, if they  21 aren't long enough, how did I --  22 THE WITNESS: Okay. Is  23 there a question?  24 BY MR. TISI:</p>

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<p style="text-align: right;">Page 450</p> <p>1 Q. Yes. So my question is, 2 Doctor, didn't you -- wasn't the issue of 3 which studies were statistically 4 significant and which ones weren't, 5 wasn't that an important factor in your 6 discussion of the talc studies in the 7 context of the consistency aspect of 8 Bradford Hill? 9 MR. LOCKE: Objection. 10 THE WITNESS: So when I 11 looked at the analyses for 12 consistency, just for sake of 13 argument, to go through this 14 quickly, let's -- I look at the -- 15 the meta-analyses of the 16 case-control studies, which is 17 statistically significant. 18 I looked at the 19 meta-analyses of the cohort 20 studies, which show no significant 21 association. And that is an 22 inconsistency. 23 BY MR. TISI: 24 Q. Okay. So the determining</p>	<p style="text-align: right;">Page 452</p> <p>1 Q. All right. Both of those if 2 you're just looking at the risk ratios 3 are positive, correct? 4 MR. LOCKE: Objection. 5 BY MR. TISI: 6 Q. 1.02 to 1.06 is a positive 7 risk ratio, correct? 8 MS. MILLER: Objection. 9 THE WITNESS: But -- but -- 10 they are positive. But again, I 11 don't see where this is playing 12 into -- 13 BY MR. TISI: 14 Q. I'm asking you the question. 15 Okay. The difference is one is 16 statistically significant result and the 17 other one is not. And you make a point 18 of that in this sentence, correct? 19 A. And that follows the point I 20 made above, which also plays into my 21 consistency is that Berge found there was 22 a statistically significant different 23 association for the perineal talc 24 powder -- or perineal/genital talc powder</p>
<p style="text-align: right;">Page 451</p> <p>1 factor, because even the cohort studies 2 had a positive risk ratio, correct? 3 A. I don't know why that plays 4 into anything. 5 Q. Well, okay. They both 6 showed a positive -- they were in your 7 report on Page 26. It was 1.02 to 1.06, 8 whereas the statistically significant 9 results from the case-control studies 10 were 1.26 to 1.35. 11 MS. MILLER: When you say 12 "they both," what are you 13 referring to? 14 BY MR. TISI: 15 Q. Okay. On Page 26 of your 16 report, you say, "There is clear 17 inconsistency between different study 18 designs with the case-control studies 19 yielding a statistically significant 20 association ranging from 1.26 to 1.35, 21 and cohort studies yielding a 22 nonstatistically significant association 23 ranging from 1.02 to 1.06, correct? 24 A. That is what it says there.</p>	<p style="text-align: right;">Page 453</p> <p>1 exposure and ovarian cancer between the 2 case-control studies and the cohort 3 studies. 4 Q. And he's looking at 5 P-values, right. P-.07? 6 A. Yeah. He is looking at 7 P-values, and that is what most of 8 medical literature does and bases their 9 evidence on. 10 And I looked -- and then I 11 look at the magnitude of the differences 12 between the two, and I do see that they 13 are different. 14 Q. Did you look to see whether 15 the confidence intervals overlapped? 16 A. What confidence intervals? 17 Q. Well, if you go above. The 18 same results here, if you go above in 19 your paragraph, it says 1.26, 95 percent 20 confidence interval 1.17 to 1.35. 21 Do you see that? You're 22 basically talking about the same dataset. 23 A. What do you mean the same 24 dataset?</p>

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<p style="text-align: right;">Page 454</p> <p>1 Q. If you go above, you said 2 1.26 to 1.35. But above, you're 3 including the confidence intervals, 4 correct? 5 A. Yes. 6 Q. Okay. The confidence 7 intervals for all of those results cross 8 1.2, for each and every one of them, 9 don't they? 10 A. I don't know how that's 11 relevant. 12 Q. I know you don't. I'm 13 asking you do they all cross 1.2? Do all 14 the confidence intervals for every one of 15 these risk ratios have 1.2 in the 16 confidence interval? 17 A. Well, I don't know what you 18 mean by in. The one from 1.02 goes from 19 .85 to 1.2. I suppose you could call 20 that in it. 21 But, yeah, if you look at 22 ranges, other than the one that it's on 23 the actual point, the ranges would 24 contain 1.2.</p>	<p style="text-align: right;">Page 456</p> <p>1 page of -- 2 Q. At the -- page -- on the 3 last page. 4 A. In the conclusions? 5 Q. Yeah, 102 -- 10 -- 6 A. Okay. I'm sorry. I didn't 7 understand. 8 Q. No, that's fine. I should 9 have oriented you. I apologize. 10 A. So the last sentence in the 11 conclusion? 12 Q. Right. And I'll read it. 13 A. Okay. 14 Q. "Why do such important 15 misconceptions about research" -- 16 A. Wait, wait, the last 17 sentence in the conclusion? Mine says 18 to the extent -- 19 Q. I'm on the conclusions. I'm 20 on the conclusions. The very -- 21 A. Oh, the first sentence. 22 Yes. 23 Q. "Why do such important 24 misconceptions about research persist?</p>
<p style="text-align: right;">Page 455</p> <p>1 Q. Okay. So all of these 2 reports are consistent in that the 3 confidence intervals include 1.2, would 4 you agree with that? 5 MR. LOCKE: Objection. 6 THE WITNESS: No I would not 7 agree with that whatsoever. 8 BY MR. TISI: 9 Q. Okay. So let me go back to 10 Dr. Rothman's statement in -- in the 11 conclusion that he says -- in the 12 conclusionary statement of his six 13 misconceptions, persistent research 14 misconceptions. 15 He says, "It's easy to 16 declare a result is not statistically 17 significant, falsely implying that there 18 is no indication of an association" -- 19 A. I -- I'm sorry. I'm just 20 stopping you because I really don't know 21 where you're reading from. 22 Q. It's the last of the 23 conclusion sentence. 24 A. Conclusion section on what</p>	<p style="text-align: right;">Page 457</p> <p>1 To a large extent these misconceptions 2 represent substitutes for more thoughtful 3 and difficult tasks. It's simpler to 4 resolve a discrepancy between a trial and 5 a non-experimental study in favor of a 6 trial without undertaking a laborious 7 analysis that Herman, et al., did. It's 8 easier to declare that a result is not 9 statistically significant, falsely 10 implying that there is no indication of 11 an association, rather than consider 12 quantitatively the range of associations 13 that the data actually support." 14 Do you see that? 15 A. I -- that those are what -- 16 those are the words. 17 Q. Okay. And the range of 18 associations for the data is represented 19 by the confidence intervals, correct? 20 A. Now, where are you reading 21 that? 22 Q. I'm asking you that 23 question. The range of associations in 24 any reported study is the numbers that</p>

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<p style="text-align: right;">Page 458</p> <p>1 are between the confidence intervals?</p> <p>2 MS. MILLER: Objection.</p> <p>3 THE WITNESS: That's not</p> <p>4 necessarily true. In the</p> <p>5 meta-analyses, we have the range</p> <p>6 of associations of the point</p> <p>7 estimates. Those are not</p> <p>8 confidence intervals.</p> <p>9 MADAM COURT REPORTER:</p> <p>10 Chris, can we go off the record</p> <p>11 for a second, just briefly?</p> <p>12 THE VIDEOGRAPHER: The time</p> <p>13 is 4:07 p.m. Off the record.</p> <p>14 (Brief pause.)</p> <p>15 THE VIDEOGRAPHER: We are</p> <p>16 back on the record. The time is</p> <p>17 4:12 p.m.</p> <p>18 BY MR. TISI:</p> <p>19 Q. Doctor, isn't it true, that</p> <p>20 the statistical -- the statistics</p> <p>21 community has abandoned the looking only</p> <p>22 at -- looking at statistical significance</p> <p>23 in favor of looking at where the</p> <p>24 confidence intervals are on studies in</p>	<p style="text-align: right;">Page 460</p> <p>1 week. I have not read that.</p> <p>2 So did you give me that</p> <p>3 statement so I can --</p> <p>4 Q. I haven't yet. I'm going to</p> <p>5 do it. But it's not just this week. Did</p> <p>6 you know in 2016 the American Statistical</p> <p>7 Association was so concerned about the</p> <p>8 misuse of statistical significance in</p> <p>9 P-values that it took the extraordinary</p> <p>10 step, never before taken before, and</p> <p>11 never before taken since, to issue a</p> <p>12 statement about the misuse of P-values</p> <p>13 and statistical significance?</p> <p>14 A. If you say that's true, I</p> <p>15 would have to see what that statement was</p> <p>16 at that time.</p> <p>17 Q. Had you ever -- had you ever</p> <p>18 heard of that?</p> <p>19 A. I --</p> <p>20 MS. MILLER: Objection.</p> <p>21 THE WITNESS: I heard</p> <p>22 that -- I may have heard there was</p> <p>23 a P-value statement. But again, I</p> <p>24 didn't read it.</p>
<p style="text-align: right;">Page 459</p> <p>1 terms of making decisions about things</p> <p>2 like causation?</p> <p>3 MR. LOCKE: Objection.</p> <p>4 THE WITNESS: So there's two</p> <p>5 different questions there. The</p> <p>6 first I heard, isn't it true that</p> <p>7 the statistical community</p> <p>8 abandoned using P-values for</p> <p>9 statistical significance.</p> <p>10 And I -- I don't think I --</p> <p>11 I'm not sure what you mean by the</p> <p>12 statistical community. But I know</p> <p>13 in the medical literature and all</p> <p>14 studies that I've worked on and</p> <p>15 all studies that I published, we</p> <p>16 had P-values in them.</p> <p>17 So I don't know who you mean</p> <p>18 by the statistical community</p> <p>19 abandoning P-values.</p> <p>20 BY MR. TISI:</p> <p>21 Q. Well, what about the</p> <p>22 American Statistical Association?</p> <p>23 A. Well, you told me that there</p> <p>24 was a statement that was just out this</p>	<p style="text-align: right;">Page 461</p> <p>1 BY MR. TISI:</p> <p>2 Q. You didn't know that?</p> <p>3 Somebody as accomplished as you in the</p> <p>4 scientific and statistical community, you</p> <p>5 don't know when the American Statistical</p> <p>6 Association position, as a member, what</p> <p>7 the position is on P-values and</p> <p>8 statistical significance?</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: I said I</p> <p>11 haven't read the statement.</p> <p>12 BY MR. TISI:</p> <p>13 Q. Did you not know that it</p> <p>14 even existed before I brought it up to</p> <p>15 you?</p> <p>16 A. Again, I didn't know what</p> <p>17 type of statement it is and the way you</p> <p>18 characterized it. As I said, I think I</p> <p>19 heard there was some things on</p> <p>20 P-values --</p> <p>21 Q. Did you bother to look it</p> <p>22 up?</p> <p>23 A. I'm on Listservs.</p> <p>24 No, I did not look it up.</p>

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<p style="text-align: right;">Page 462</p> <p>1 MS. MILLER: Objection. 2 BY MR. TISI: 3 Q. So having heard there was a 4 statement about statistical significance 5 and P-values by the American Statistical 6 Association, it wasn't important for you 7 to look it up and see, well, what do my 8 colleagues say about this? 9 A. I don't think it's a matter 10 of importance. I think it's a matter of 11 time. And you know, I -- when that came 12 out, I may have thought, oh, that's 13 something worth looking at. But, you 14 know, my time got consumed by more 15 pressing matters, and I never got to it. 16 Q. This came out in 2016. This 17 is 2019. You mean you had no time in the 18 past three years to look at a 19 two-three-page statement about the misuse 20 of P-values and statistical significance? 21 MS. MILLER: Objection. 22 THE WITNESS: That's not 23 what I said or meant. What I 24 meant is that at the time it came</p>	<p style="text-align: right;">Page 464</p> <p>1 because all the studies I looked 2 at were talking about statistical 3 significance. So it would be odd 4 if I didn't talk about statistical 5 significance. 6 Can you show me a report 7 where there wasn't a P-value in 8 the studies I reviewed. 9 BY MR. TISI: 10 Q. I'm asking you the 11 questions. I'm asking you the questions. 12 And the question that I'm asking you is, 13 since you were doing a whole causation 14 analysis, looking at the totality of the 15 evidence, 30-some odd studies and dealing 16 with an issue of consistency, and relying 17 on statistical significance, not for one 18 study, but looking across studies, 19 looking across design, did you not think 20 it important to say, you know, I remember 21 that the American Association for -- 22 American Statistical Association came out 23 with this really unique statement. Maybe 24 I ought to pick it up and take a look at</p>
<p style="text-align: right;">Page 463</p> <p>1 out, I likely thought, oh, if I 2 ever have a spare minute, this 3 would be something interesting to 4 look at. But I don't think I came 5 out with -- I -- the spare minute 6 probably may have happened later. 7 But by that point, I had forgotten 8 about it. 9 BY MR. TISI: 10 Q. Well, in the interim you had 11 written two reports, one in 12 Viagra/Cialis -- Cialis outside of your 13 work and one here for 56 hours or 14 whatever it happened to be. 15 And you mentioned 16 statistical significance a lot in your 17 report. 18 Could you have taken one of 19 those hours to look up what the American 20 Statistical Association says about 21 statistical significance? 22 MS. MILLER: Objection. 23 THE WITNESS: I'm not sure 24 how that would be relevant,</p>	<p style="text-align: right;">Page 465</p> <p>1 it? 2 MR. LOCKE: Objection. 3 THE WITNESS: Again, I don't 4 see how that's relevant, because 5 to do the analyses I've done, I 6 rely upon how the papers report 7 their results and so forth. And I 8 can't impose sort of a different 9 way for them to analyze their 10 data. 11 BY MR. TISI: 12 Q. They didn't do -- they 13 didn't do Bradford Hill tests, did they? 14 You did. You did in this litigation. 15 All the studies, very -- none of these 16 studies did a Bradford Hill -- Bradford 17 Hill analysis, but you did, true? 18 MS. MILLER: Objection. 19 THE WITNESS: I don't know 20 how P-values are relevant just to 21 Bradford Hill. I don't get that. 22 BY MR. TISI: 23 Q. You applied your own 24 independent -- independent expertise as a</p>

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<p style="text-align: right;">Page 466</p> <p>1 statistician at a medical university and 2 you are unaware what the American 3 Statistical Association says about 4 P-values? 5 MS. MILLER: Objection. 6 THE WITNESS: Again, I 7 looked at all the literature that 8 exists. And I -- I used the 9 Bradford Hill criteria to 10 determine whether or not there is 11 a causal relationship between 12 perineal talc exposure and ovarian 13 cancer. 14 And the methodology that I 15 used is the methodology that all 16 others use. And so I don't see 17 the relevance of having to look 18 up -- or I don't see the relevance 19 of looking up a statement on 20 P-values to do that analyses. 21 BY MR. TISI: 22 Q. You know that looking at the 23 plaintiffs' experts reports they -- you 24 clearly were critical of the plaintiffs'</p>	<p style="text-align: right;">Page 468</p> <p>1 Q. Is that a criticism -- 2 MS. MILLER: And also talk 3 over me. 4 MR. TISI: I'm going to talk 5 because -- 6 MS. MILLER: Do you just 7 talk over all women? 8 MR. TISI: Oh, please don't 9 do that to me. I have no problem 10 with you -- with you objecting. 11 But your constant speaking 12 objections are -- are really 13 overboard. 14 BY MR. TISI: 15 Q. Doctor -- 16 MS. SHARKO: I don't think 17 the record will demonstrate that. 18 MR. TISI: I think the 19 record will demonstrate that. 20 BY MR. TISI: 21 Q. Doctor, did you -- isn't one 22 of your criticisms of the plaintiffs' 23 experts, one of them, is that they -- 24 they were looking at the point estimate</p>
<p style="text-align: right;">Page 467</p> <p>1 experts for looking at the point 2 estimates and not considering the -- 3 whether a study was statistically 4 significant or not, true? 5 A. Can you point me to -- 6 Q. I'm asking whether that's 7 true. We can go through it. I'm asking 8 you, was that -- or is that one of your 9 criticisms? 10 A. Well, you told me that was a 11 criticism. 12 Q. Is it a criticism? 13 A. I'm asking you show me in my 14 report where that -- 15 Q. Is that a criticism? 16 A. I can't -- 17 MS. MILLER: Please don't 18 talk over the witness. 19 BY MR. TISI: 20 Q. Is that -- is that a 21 criticism of yours -- 22 MS. MILLER: How many times 23 do I have to say it? 24 BY MR. TISI:</p>	<p style="text-align: right;">Page 469</p> <p>1 and not the -- of these studies for 2 consistency, and not considering whether 3 or not they were statistically 4 significant or not? I'm asking you, is 5 that -- as you sit here today, is that 6 one of your criticisms? 7 A. I'm asking you to point that 8 out to me, because you -- 9 Q. I'm asking you -- I'm asking 10 you, is that one of your criticisms? 11 A. I -- I'll have to read 12 through all my criticisms. I'm happy to 13 do so. 14 Q. I thought you would have 15 done that in preparation for today. 16 A. Yeah, and I'm tired. And 17 it's a long day, and I don't -- I did not 18 memorize my, you know, 40-some-page 19 report. So I will -- 20 Q. When's the last time you -- 21 A. I will take the time and go 22 through and -- 23 Q. When was the last time that 24 you read it before today?</p>

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<p style="text-align: right;">Page 470</p> <p>1 MS. MILLER: She's in the 2 middle of a sentence again. 3 BY MR. TISI: 4 Q. When's the last time you 5 read it before today? 6 MR. TISI: This is a 7 filibuster, and you know it. 8 THE WITNESS: I'm trying to 9 answer your question. And you're 10 asking me if I made that 11 criticism. And I'm saying that I 12 can't remember off the top of my 13 head. 14 BY MR. TISI: 15 Q. Okay. 16 A. And if you know where it is 17 in here, that I made that criticism, I 18 ask for the help. You said no, I'm not 19 going to do that. You need to remember 20 that. And -- 21 Q. I didn't say that. 22 A. Well, that's how I 23 interpreted it. 24 Q. Okay.</p>	<p style="text-align: right;">Page 472</p> <p>1 MS. MILLER: Would you like 2 me to re-read? 3 MR. TISI: No. She's not 4 asking to re-read. You are. 5 THE WITNESS: Well, I am. I 6 am. I'm confused. What is the 7 question? 8 BY MR. TISI: 9 Q. Doctor -- doctor -- okay. 10 Do you have an opinion to a reasonable 11 degree of scientific certainty that the 12 plaintiffs' experts were wrong and used 13 an improper methodology if they looked at 14 the point estimates for consistency and 15 did not consider statistical 16 significance? If that was shown to be 17 true, would that be wrong? 18 A. I think if someone only 19 looked at point estimates and did not 20 look at statistical significance, that 21 would be incorrect. 22 Q. Okay. What if they looked 23 at the point estimate and the confidence 24 interval, irrespective of statistical</p>
<p style="text-align: right;">Page 471</p> <p>1 A. And then I said, well, okay, 2 then I'll have to go through and read to 3 see if I made that criticism. 4 Q. Okay. As you sit here 5 today, okay, because honestly, I don't 6 have the time to go through this. But I 7 know it's in there. 8 A. Well, then please show it to 9 me. 10 Q. I said I know it's in there, 11 and I don't have the time to go through 12 it. But I'm asking you, as you sit here 13 today, do you have an opinion to a 14 reasonable degree of scientific certainty 15 that the plaintiffs' experts were wrong 16 and used an improper methodology if they 17 looked at the point estimates and did not 18 consider statistical significance? If 19 that were shown to be true, would that be 20 wrong? 21 MS. MILLER: Objection. If 22 what was shown to be true? 23 MR. TISI: Read the 24 question, Counsel.</p>	<p style="text-align: right;">Page 473</p> <p>1 significance? 2 A. Again, I'd have to see the 3 analyses. The analyses that I looked at 4 in terms of consistency was 5 methodologically flawed. 6 Q. Okay. Let's look at the ASA 7 statement on P-values. If you go to the 8 "ASA statement on P-values: Context and 9 purpose, the editorial." 10 Do you see that? Second 11 page. 12 A. I don't have that document. 13 Q. It's right in front of you, 14 I believe. 15 A. 28? 16 Q. Mm-hmm. 17 A. Second page? 18 Q. Yep. It says, "ASA 19 statement on P-values: Context, process, 20 and purpose." 21 A. Okay. 22 Q. And if you go down -- and 23 I'm just going to ask you one question 24 here, so I don't think it's necessary for</p>

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<p style="text-align: right;">Page 474</p> <p>1 you to read the whole thing. 2 It says, "When the ASA board 3 decided to take up" -- at the very last 4 paragraph at the bottom of the left 5 column. "When the ASA board decided to 6 take up the challenge of developing 7 policy statements on P-values and 8 statistical significance, it did so 9 recognizing this was not a lightly taken 10 step. The ASA has not previously taken 11 positions on specific matters of 12 statistical practice." 13 Is that true? I mean, is 14 that -- did I read that correctly? 15 A. You read the words, yes. 16 Q. Okay. Have you ever seen 17 the ASA do -- issue a statement other 18 than what I've just presented you here, 19 about statistical practice? 20 A. Well, they state that they 21 previously -- have not previously taken 22 positions. So if what they are saying is 23 true, there would be nothing to see. 24 Q. Okay. And if you look at</p>	<p style="text-align: right;">Page 476</p> <p>1 please? 2 Q. Page 131. We are at the 3 bottom, 63.4. 4 A. Okay. Yes, I'm there. 5 Q. Do you see Number 2 where it 6 says, "P-values" -- and let me ask you if 7 this is a true statement or not. 8 "P-values do not measure the probability 9 that a study hypothesis is true or the 10 probability that the data was produced by 11 random chance alone." 12 Do you see that? 13 A. Yes, I do. 14 Q. Okay. It says, "Researchers 15 often wish to turn P-values into a 16 statement the truth of a null hypothesis 17 or about the probability that random 18 chance produced the overall data. The 19 P-value is neither. It is a statement 20 about the data in relation to a specified 21 hypothetical explanation and it is not a 22 statement about the explanation itself." 23 Is that true? 24 A. Yeah, I -- I'll have to</p>
<p style="text-align: right;">Page 475</p> <p>1 the next page, some of the people who 2 were involved in this are, among other 3 people, Sander Greenland, and Kenneth 4 Rothman. You see their names there? 5 A. I'm sorry. Where are you? 6 Q. Next page. Do you see the 7 bullet points on the right? 8 A. Yeah. There's a list of 9 individuals. Yes, I see that. 10 Q. Among them Sander Greenland, 11 Kenneth Rothman, the two people that 12 we've been talking about all day, 13 correct? 14 A. So, again, can you point 15 me -- you mean these bullets? 16 Q. Yeah. 17 A. Well, these are references. 18 Q. Okay. All right. If you go 19 to the next page, the ASA statements on 20 statistical significance. 21 A. On what page? Could you 22 just -- 23 Q. Next page. 24 A. -- say the page number,</p>	<p style="text-align: right;">Page 477</p> <p>1 parse it in different ways. 2 So it is true that the 3 P-value is not the truth about a 4 hypothesis. To calculate a P-value, you 5 need to assume the hypothesis is true. 6 Therefore, it can't be the 7 probability that the hypothesis is true 8 because you assumed it was true. So, 9 yes, I agree with that. 10 Q. But it also says -- 11 THE VIDEOGRAPHER: Chris, 12 watch your -- watch your 13 microphone. Sorry. 14 BY MR. TISI: 15 Q. But it also says it is not a 16 statement of the truth of the null 17 hypothesis. 18 A. That's what I mean. You're 19 assume the null hypothesis is true in 20 order to calculate a P-value. So 21 therefore the P-value cannot be the 22 probability the null hypothesis is true 23 because that was the assumption to get 24 the P-value.</p>

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<p>1 Q. The next statement is</p> <p>2 "Scientific conclusions and business</p> <p>3 policy decisions should not be based only</p> <p>4 on whether a P-value passes a specific</p> <p>5 threshold. Practices that reduce data</p> <p>6 analysis to scientific inferences to</p> <p>7 mechanical bright-line rules, i.e.,</p> <p>8 P-value .05 for justifying scientific</p> <p>9 claims and conclusions, can lead to</p> <p>10 enormous beliefs and poor decisionmaking.</p> <p>11 "A conclusion does not</p> <p>12 immediately become true on one side of</p> <p>13 the divide and false on the other."</p> <p>14 Do you agree with that?</p> <p>15 A. I agree that you read the</p> <p>16 sentence. And I go on, and what makes</p> <p>17 me -- this true is researchers should</p> <p>18 bring many contextual factors into play</p> <p>19 to derive scientific inferences,</p> <p>20 including the design of a study, the</p> <p>21 quality of the measurements, the external</p> <p>22 elements for the phenomenon under study,</p> <p>23 and the validity of the assumptions that</p> <p>24 underlie the data analysis. And to me,</p>	<p>1 sentence says --</p> <p>2 A. No, no, no. Very end of</p> <p>3 what?</p> <p>4 Q. The very end of the</p> <p>5 conclusion section.</p> <p>6 A. On a different page now?</p> <p>7 Q. On a different -- next page.</p> <p>8 The next sentence says, "No single index</p> <p>9 should substitute for scientific</p> <p>10 reasoning."</p> <p>11 Do you agree with that?</p> <p>12 A. I haven't -- again, that's</p> <p>13 taken out of context. I agree with the</p> <p>14 whole thing that's, "Good statistical</p> <p>15 practice is an essential component of</p> <p>16 good scientific practice, emphasizes</p> <p>17 principles of good study design and</p> <p>18 conduct, a variety of numerical and</p> <p>19 graphical summaries of data,</p> <p>20 understanding the phenomenon under study,</p> <p>21 and interpretation of results in context,</p> <p>22 complete reporting and proper and logical</p> <p>23 quantitative understanding of what the</p> <p>24 data summaries mean."</p>
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<p>1 this sort of encompasses what the</p> <p>2 Bradford Hill framework is doing.</p> <p>3 Q. And let's read the rest of</p> <p>4 it. It goes on to say, "Pragmatic</p> <p>5 considerations often require binary yes</p> <p>6 and no decisions, but does not mean that</p> <p>7 the P-value alone can ensure that a</p> <p>8 decision is correct or incorrect. The</p> <p>9 widespread use of statistical</p> <p>10 significance, generally interpreted as a</p> <p>11 P-value less than or equal to .05, is a</p> <p>12 license for making a claim of a</p> <p>13 scientific finding or implied truth,</p> <p>14 leads to considerable distortion of the</p> <p>15 scientific process."</p> <p>16 Is that true or not?</p> <p>17 A. That is true in the context</p> <p>18 of what they mean in that you cannot use</p> <p>19 a single study to say this study was</p> <p>20 statistically significant, therefore, I</p> <p>21 have proven something scientifically, a</p> <p>22 single study.</p> <p>23 Q. Okay. At the very end of</p> <p>24 it, on conclusion, it says -- at the last</p>	<p>1 Q. And then the next sentence</p> <p>2 says?</p> <p>3 A. "No single index" -- I don't</p> <p>4 know what they're referring to there. It</p> <p>5 doesn't say the P-value alone -- "should</p> <p>6 substitute for scientific reasoning." It</p> <p>7 says no single index. It could be any</p> <p>8 index, the mean.</p> <p>9 Q. Now, do you know that the</p> <p>10 American Statistical -- and you were not</p> <p>11 asked to be on this panel, I assume,</p> <p>12 since you didn't even know that -- you</p> <p>13 hadn't even read it. So you were not on</p> <p>14 this panel. You were not asked by your</p> <p>15 colleagues to participate in this,</p> <p>16 correct?</p> <p>17 MS. MILLER: Objection.</p> <p>18 Please let me object.</p> <p>19 THE WITNESS: Could you show</p> <p>20 me who was on the panel?</p> <p>21 BY MR. TISI:</p> <p>22 Q. I'm just asking you, were</p> <p>23 you asked to be on this panel?</p> <p>24 A. I -- I -- yeah, I don't know</p>

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<p>1 how -- who is on the panel and how many 2 people are on the panel. 3 Q. I didn't ask you that. 4 A. But I have a feeling that 5 there are many people that weren't on the 6 panel. 7 Q. I didn't ask that. I asked 8 whether you were asked to be on the 9 panel. 10 A. No, I was not asked to be on 11 the panel. 12 Q. That was the answer to the 13 question. Thank you. 14 Next question is -- now, I 15 represented to you that this week the 16 American -- you know, -- do you get the 17 journal, the American Statistician? 18 A. Yes. 19 Q. It's probably the most 20 important journal in the statistical -- 21 in the field of statistics. Would you 22 agree? 23 MS. MILLER: Objection. 24 BY MR. TISI:</p>	<p>1 important statistics journal that there 2 is. I think it depends upon -- no. I -- 3 Q. Did you know just this week, 4 as I indicated, that the journal devoted 5 its entire volume to the issue of 6 statistical significance? 7 A. So this week's journal? 8 Q. Mm-hmm. 9 A. And, you know, I don't even 10 know if I had been in my office to get 11 it. So I am not aware of that. 12 Q. You weren't aware that it 13 was coming out, were you? 14 A. I don't know why I would be 15 aware that it's coming out. 16 Q. Sometimes if something big 17 is happening in the world of statistics, 18 kind of a lot of people involved, it gets 19 out that they are putting together a 20 volume devoted to a specific topic. 21 You didn't -- you were 22 unaware of it? 23 A. I -- well, I -- I don't know 24 if that statement is true or not. I</p>
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<p>1 Q. It's a high-impact journal 2 within that field? 3 MS. MILLER: Objection. 4 THE WITNESS: Wait, what's 5 the journal again? 6 (Document marked for 7 identification as Exhibit 8 Ballman-28.) 9 BY MR. TISI: 10 Q. The American -- the 11 American -- what's the journal of the 12 American Statistical Society? 13 A. What is the journal? The 14 journal -- JASA. 15 Q. Yeah. Actually, just give 16 me the -- I'm sorry. I apologize. 17 A. JASA, I believe, is the 18 Journal of ASA. The Journal of the 19 American Statistical -- 20 Q. It's the American 21 Statistician. The American Statistician. 22 A. Yeah, that's sort of a -- I 23 get that journal. I don't know if people 24 would characterize it as the most</p>	<p>1 mean, I know in JCO, we put out very -- 2 we put out special issues. And I don't 3 think all of oncology is aware it's 4 coming out. 5 Q. So I'm going to show you in 6 the -- is the journal Science a good 7 journal? Sorry. Nature. I'm sorry. 8 A. Yes. Nature is a very good 9 journal. 10 Q. The entire ASA journal was 11 devoted to 43 studies, 43 papers on this 12 topic. 13 MS. MILLER: What's ASA? 14 MR. TISI: The American 15 Statistical Association. 16 MS. MILLER: That's not a 17 journal. That's an association. 18 You said -- 19 MR. TISI: You're 20 interrupting me now. 21 MS. MILLER: Fine. 22 MR. TISI: Their journal is 23 the American Statistician. 24 MS. MILLER: I think she</p>

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<p>1 said that's not their journal. 2 THE WITNESS: No, I didn't 3 say that. 4 MS. MILLER: Oh, I 5 misunderstood. 6 THE WITNESS: I said I don't 7 believe it's the most important. 8 Could -- I don't know if 9 there's 40-some articles. 10 BY MR. TISI: 11 Q. I'm going to represent to 12 you that it is. 13 And I'm -- you know, you can 14 either believe me or not. My guess is at 15 some point this week, you may go home and 16 take a look at it. But I didn't bring 17 all 43 articles. And you'd want to read 18 them all anyway. So we don't have the 19 time to do that. 20 A. But I'd at least like to 21 look at the titles. 22 MR. TISI: Okay. Well, John 23 can you pull up the titles of the 24 43? If you can get them on your</p>	<p>1 MS. MILLER: Objection. 2 That was not read correctly. 3 BY MR. TISI: 4 Q. These three authors and more 5 than 800 signatories call for an end to 6 hyped claims and the dismissal of 7 possibly crucial effects. 8 Do you see that? 9 A. I see how that's stated 10 there. 11 Q. Okay. And I'm happy to give 12 you an opportunity to read it. And since 13 you haven't read it, and this will take a 14 moment, I'm happy to do it, but I am 15 going to focus your attention to certain 16 things. 17 Do you want to glance 18 through it, I'm more than happy to have 19 you glance through it, but we can do it 20 off the record. 21 MR. TISI: Go off the 22 record, please. 23 MR. LOCKE: No, no. 24 MR. TISI: That's what we've</p>
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<p>1 computer, please. 2 BY MR. TISI: 3 Q. But in the meantime, a 4 commentary related to this, this 5 publication was published in Nature by 6 Drs. Greenland, Blake McShane and 7 Valentin Amrhein. 8 (Document marked for 9 identification as Exhibit 10 Ballman-29.) 11 BY MR. TISI: 12 Q. Okay. Let me show you that. 13 Now, the title of this is "Retire 14 Statistical Significance." 15 Do you see that, Doctor? 16 A. It says "Retire Statistical 17 Significance." 18 Q. Okay. And actually, 19 underneath it says, Valentin Amrhein, 20 Sander Greenland, and Blake McShane, and 21 more 800 signatories, call for an end to 22 hyped up claims and dismissal -- 23 dismissal of possibly crucial effects. 24 Do you see that?</p>	<p>1 done -- if it's a long -- 2 MR. LOCKE: No, we have not. 3 MR. TISI: Yes, we have. 4 MR. LOCKE: No, we have 5 not-- 6 MR. TISI: Yes, we have. 7 Yes, we have. 8 MS. MILLER: I thought we go 9 off the record if it's something 10 the witness -- 11 MR. TISI: Hadn't seen, 12 yeah. 13 MS. MILLER: No, if it was 14 something the witness had cited 15 and a reference. But if it's 16 something the witness had never 17 seen before, I don't think we'd go 18 off -- 19 MR. TISI: No, that's what 20 we -- that's what we've been 21 doing. 22 MR. LOCKE: That's not what 23 we've been doing. 24 MR. TISI: That's exactly</p>

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<p style="text-align: right;">Page 490</p> <p>1 what we've been doing.  2 Anyway, she's looking at it.  3 BY MR. TISI:  4 Q. Let's go through. I'm going  5 to ask you to read down to the bottom of  6 the left-hand column. I'll ask you some  7 questions about that.  8 A. How far do you want me to  9 read?  10 Q. Just to the bottom of the  11 left-hand column?  12 A. Second page?  13 Q. Second page, correct.  14 A. Okay. Just the bottom of  15 that first column.  16 Q. Correct.  17 A. I have read that.  18 Q. Actually, and you can  19 continue to the next -- the first  20 paragraph on the next page.  21 MS. MILLER: The first  22 paragraph on the next column or  23 the --  24 MR. TISI: Next column.</p>	<p style="text-align: right;">Page 492</p> <p>1 that I actually know is Sander  2 Greenland. I do not know who  3 Blake McShane is, nor Valentin  4 Amrhein.  5 BY MR. TISI:  6 Q. Do you know -- do you have  7 respect for Sander Greenland?  8 MS. MILLER: Objection.  9 THE WITNESS: Again, I know  10 his name. I know he's done -- you  11 know, he's authored some books and  12 so forth.  13 BY MR. TISI:  14 Q. So what they say here -- and  15 of course, I'm reading in the second  16 page. It says, "We agree" -- "We are far  17 from alone. We invited others to read  18 this draft" -- "read a draft of this  19 comment and sign their names if they  20 concurred with our message. 250 did so  21 within 24 hours. A week later, we had  22 more than 800 signatories, all checked  23 for academic affiliation or other  24 indication of present or past work in a</p>
<p style="text-align: right;">Page 491</p> <p>1 BY MR. TISI:  2 Q. Actually, you can read the  3 whole -- read the whole column up until  4 the next category.  5 A. Yes. I read it.  6 Q. So, Doctor, under the  7 section that says -- first of all, these  8 are all -- these authors are all people  9 that you know in your field, correct?  10 A. I've heard of their names.  11 Q. Okay. These are all widely  12 respected statisticians and  13 epidemiologists, correct?  14 MS. MILLER: Objection.  15 MR. LOCKE: Objection.  16 THE WITNESS: I -- I -- I  17 can't speak to what respect they  18 do or they do not have. I know  19 their names.  20 BY MR. TISI:  21 Q. And do you have respect for  22 them?  23 MS. MILLER: Objection.  24 THE WITNESS: The only name</p>	<p style="text-align: right;">Page 493</p> <p>1 field that depends on statistical  2 modeling."  3 Do you see that?  4 A. That's what it says there.  5 Q. Okay. So this has been  6 endorsed by 800 of your colleagues?  7 MR. LOCKE: Objection.  8 BY MR. TISI:  9 Q. Correct?  10 A. I don't know who the 800  11 people are.  12 Q. Okay. And they say, "The  13 pervasive problem" -- here on Page 1,  14 says, "Let's be clear about what must  15 stop. We should never conclude that  16 there is no difference or no association  17 just because a P-value is larger than a  18 threshold of .05, or equivalently because  19 a confidence interval includes zero.  20 "Neither should we conclude  21 that two studies conflict because one had  22 a statistically significant result and  23 the other did not. These errors waste  24 much research efforts and misinform</p>

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<p style="text-align: right;">Page 494</p> <p>1 policy decisions." 2 Do you see that? 3 A. That's what they say. 4 Q. Do you agree? 5 A. I -- I -- I don't know if I 6 agree or not. I mean, I have to read 7 this more through more carefully. There 8 are some aspects that I agree. I agree 9 that, you know, it's wrong to conclude 10 that two studies conflict because one has 11 statistically significant results or not. 12 So I agree with the example 13 that they give, null or one has a risk 14 ratio of 1.2, that it is statistically -- 15 that has -- that is statistically 16 significant, or just is not statistically 17 significant by the .05 level if P-value 18 of .091. 19 Another one also has a risk 20 ratio of 1.2, so similar risk ratios. 21 And its P-value is statistically 22 significant. So I agree that I would not 23 conclude that those two studies conflict. 24 Q. And they result -- and they</p>	<p style="text-align: right;">Page 496</p> <p>1 Q. Okay. But their statement 2 is definitive. They're not hedging at 3 all? They're saying don't do this. 4 MS. MILLER: Objection. 5 THE WITNESS: They are 6 hypothesizing. 7 BY MR. TISI: 8 Q. They are not hypothesizing. 9 They're saying let's be clear about what 10 must stop. 11 A. That, they're clear about. 12 But again, if I could -- you asked me if 13 I agree with this statement. And you cut 14 me off when I said that they are 15 hypothesizing. So may I finish that? 16 Q. Sure. 17 A. So they are hypothesizing by 18 saying eradicating -- and I'm surprised 19 statisticians are doing this. 20 "Eradicating categorization will help to 21 halt overconfident claims, unwarranted 22 declarations of no difference, and absurd 23 statements about replication failure. 24 I don't see any evidence.</p>
<p style="text-align: right;">Page 495</p> <p>1 talk about the American Statistical 2 Association in the statement that we just 3 read from 2016, right? The associated 4 statement in the American Statistician, 5 warning against the misuse of statistical 6 significance. And that was what we just 7 talked about as Exhibit Number -- 8 A. 28. 9 Q. -- 28, correct? 10 A. They cite that statement, 11 yes. 12 Q. And it says, "Eradicating 13 categorization will help halt" -- 14 A. Now where do you -- where 15 are you now? 16 Q. In the middle. In the blue. 17 A. Okay. 18 Q. "Eradicating categorization, 19 will help halt overconfident claims, 20 warranted claims of no different and 21 absurd statements about replication 22 failure." 23 Do you agree with that? 24 A. Again, I think it depends.</p>	<p style="text-align: right;">Page 497</p> <p>1 This is a hypothesis, that doing this is 2 going to stop this. I don't see any 3 evidence here, unless it's in here, which 4 I haven't been able to read in detail, 5 that there's evidence doing so is going 6 to prevent these things. 7 Q. Let's go to the next page. 8 And there's a paragraph that I want you 9 to read. I'm going to ask you to read it 10 in entirety because it deals with an 11 issue that we talked about before. 12 Go to the next page. It 13 says under the term second on the 14 left-hand side. And it says -- and I'll 15 read it into the record. 16 "Second, not all values 17 inside" -- they're talking about inside 18 the confidence interval -- are equally 19 compatible with the data, given the 20 assumptions. 21 "The point estimate is the 22 most compatible, and the values near it 23 or more compatible than those at the 24 outer" -- "near the limits. That is why</p>

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<p style="text-align: right;">Page 498</p> <p>1 we urge authors to discuss the point 2 estimate, even when we have large 3 P-values or a wide interval, as well as 4 discussing the limits of that interval. 5 "For example, authors above 6 could have written, "Like a previous 7 study our results suggest a 20 percent 8 increased risk on new onset atrial 9 fibrillation in patients given 10 antiinflammatory drugs. Nonetheless, the 11 risk difference ranging from a 3 percent 12 decrease, a small negative association, 13 to a 48 percent increase, a substantial 14 positive association, is also reasonably 15 compatible with our data. 16 "Interpreting the point 17 estimate while acknowledging its 18 uncertainty will keep you from making 19 false declarations of no difference and 20 then making overconfident claims." 21 Do you see that? 22 A. I -- that's what it says 23 there. 24 Q. Okay. Now, let's go back to</p>	<p style="text-align: right;">Page 500</p> <p>1 the number? 2 THE WITNESS: And after 3 that, and I'm willing to do this. 4 But I do need a bathroom break. 5 That water I drank. 6 Yes, I have it. 7 MR. SOILEAU: It's 26. 8 MS. MILLER: I got it. 9 THE WITNESS: We have it. 10 BY MR. TISI: 11 Q. First, we talked about -- 12 the comment that we talked about before 13 if you look at the -- the most likely, do 14 you agree with the statement in this, 15 "The point estimate is the most 16 compatible with" -- "and the values near 17 it are more compatible than those near 18 the limits in terms of the true risk." 19 A. Yeah, so can I place 20 something -- it says compatible with the 21 data. It doesn't say compatible with the 22 truth. We don't know the truth. 23 So compatible with the data, 24 I agree. Compatible with the truth, I do</p>
<p style="text-align: right;">Page 499</p> <p>1 talk about talc. First of all, do you 2 agree with that? 3 A. Again, I -- I would need to 4 read. I don't know what study they are 5 talking about above. I mean, I think 6 I -- 7 Q. Well, they're talking about 8 the one we read on the prior page, the 9 example that we read on the prior page 10 with the example that we talked about -- 11 that was talked about, that I asked you 12 to read before. 13 A. So I'm not comfortable 14 agreeing or disagreeing with something 15 that I was just handed and told, okay, 16 you have a few minutes to read through 17 this, you know, quickly and not have time 18 to think about it. So I'm just not 19 comfortable saying whether I agree or 20 not. 21 Q. Well, let's go to 22 Dr. Merlo's chart if we could, back to 23 that. 24 MS. MILLER: Do you remember</p>	<p style="text-align: right;">Page 501</p> <p>1 not agree because we don't know the 2 truth. And we're just trying to estimate 3 it with the data. But it could be 4 drastically wrong, like if there are 5 recall biases and selection biases. 6 Q. But one of the things that 7 statisticians do is they say, look at the 8 whole confidence interval, right? They 9 say, here, the real thing that you really 10 need to do is look at the range 11 represented by the confidence interval. 12 A. I think -- yeah, they're 13 just saying one should look at the 14 uncertainty in the estimate by looking at 15 the confidence interval. 16 Q. Okay. And the example they 17 give is, if the confidence interval goes 18 from a negative, and like a .97 all the 19 way up to a 1.48, that you should talk 20 about the fact that, yes, it crosses 21 zero. And you might have some risk that 22 is negative. But most of the risk lies 23 in the positive area. 24 A. Yeah, I don't know where you</p>

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<p style="text-align: right;">Page 502</p> <p>1 are getting that confidence interval. I 2 don't see a .97. 3 Q. It says here, "Nonetheless, 4 the risk difference ranging from a 3 5 percent decrease" -- 6 A. Oh, I see. 7 Q. -- "a small negative 8 association" -- 9 A. Okay. 10 Q. -- "to a 48 percent" -- "a 11 substantial" -- 12 A. I see. So you took one 13 minus 3 percent. I got it. I'm with 14 you. 15 Q. Okay. Okay. And so what 16 they're saying is you look at the 17 entirety of the confidence interval and 18 use your judgment. And you don't rely on 19 a snap decision of saying statistically 20 significant or not, true? 21 A. Say -- ask the question 22 again. 23 Q. They're saying you don't 24 just flip a switch on statistical</p>	<p style="text-align: right;">Page 504</p> <p>1 to the exhibit with Dr. Merlo's exhibit 2 there. Would you please take for me, if 3 you could -- I'm going to give you this 4 pen. And would you please highlight for 5 me every single risk ratio that's above 6 one? 7 MS. MILLER: Objection. 8 THE WITNESS: The risk ratio 9 itself? 10 BY MR. TISI: 11 Q. Yes. 12 A. I'm sorry. I goofed. 13 MS. MILLER: Can you give a 14 new one? She made a mistake. 15 THE WITNESS: Can I color it 16 in green or something so -- 17 BY MR. TISI: 18 Q. Yeah, color it -- well, why 19 don't we put an X by it. This way we'll 20 know. Which one did you do it wrong? 21 A. The last one. 22 Q. Okay. That's Gonzalez. For 23 the record, Gonzalez is not greater than 24 one, correct?</p>
<p style="text-align: right;">Page 503</p> <p>1 significance. They say you look at the 2 entirety of the confidence interval in 3 the context of everything, correct? 4 A. Yeah. They're saying one -- 5 one can report the confidence interval so 6 that you know the uncertainty that's 7 associated with the point estimate. 8 MS. MILLER: Okay. I think 9 she asked for a break. 10 MR. TISI: Sure. Although 11 we're in the -- yeah, if you need 12 to do a break, we'll do that. 13 THE WITNESS: It can only be 14 like two minutes. 15 THE VIDEOGRAPHER: All 16 right. Stand by, please. Remove 17 your microphones. The time is 18 4:48 p.m. Off the record. 19 (Short break.) 20 THE VIDEOGRAPHER: We are 21 back on the record. The time is 22 4:54 p.m. 23 BY MR. TISI: 24 Q. Doctor, if you can go back</p>	<p style="text-align: right;">Page 505</p> <p>1 MS. MILLER: Objection. 2 THE WITNESS: Yes, that's 3 correct. 4 BY MR. TISI: 5 Q. So now -- 6 A. The risk ratio. 7 Q. Now, the next thing that 8 Dr. Greenland and his colleagues point 9 out here is that we look at the 10 confidence interval, correct? 11 A. What do you mean by the next 12 thing? 13 Q. Well, one of the things he 14 says, you need to look not at statistical 15 significance so much as the confidence 16 interval, correct? 17 A. Where is that statement? 18 Q. Well, he says here, he says, 19 "The point estimate is the most 20 compatible value and the values near the 21 most comparable" -- "comparable than 22 those near the limits. That's why you 23 urge authors to discuss the point 24 estimate even when you have a large</p>

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<p style="text-align: right;">Page 506</p> <p>1 P-value or wide interval." 2 Okay. And then he talks 3 below about where the confidence interval 4 rates go, correct? 5 A. Well, you didn't quite 6 complete that sentence. So when they 7 have a large P-value or wide interval as 8 well as discussing the limits of the 9 interval. 10 Q. Okay. So let's discuss the 11 limits of the interval for a moment. 12 A. Okay. 13 Q. Okay. I'm going to ask you, 14 if you wouldn't mind, to circle every 15 P-value on -- every confidence interval 16 that includes 1.2 -- actually, let me use 17 a black pen, use that -- that includes 18 1.2 either as -- within the upper or 19 lower bounds. 20 A. Every confidence interval? 21 Q. Yeah, where 1.2 is within 22 the confidence interval. I'll ask you to 23 do one other thing. This is the last 24 thing I'll asked you to do with art.</p>	<p style="text-align: right;">Page 508</p> <p>1 numbers on the page, for most of 2 these, are greater than one. 3 BY MR. TISI: 4 Q. Okay. Would you also agree 5 that irrespective of design, every one of 6 these -- every one of these studies that 7 you highlighted in yellow, the vast 8 majority of -- excuse me, highlighted in 9 red -- 10 A. Pink. 11 Q. -- pink are consistent with 12 a 20 percent increased risk of ovarian 13 cancer? 14 MS. MILLER: Objection. 15 THE WITNESS: That I 16 disagree with. 17 BY MR. TISI: 18 Q. Okay. Why would you say 19 that? 20 A. Because we know that 21 population-based case-control studies -- 22 or, sorry, case-control studies and -- 23 well, and to some degree the cohort 24 studies have confounding and bias in</p>
<p style="text-align: right;">Page 507</p> <p>1 Take this blue pen, and 2 would ask you to put a mark by the side 3 of anything that in any of those studies 4 that include within the confidence 5 interval of 1.25? 6 MS. MILLER: Objection. 7 BY MR. TISI: 8 Q. Or maybe you can highlight 9 the inside of the -- however you want to 10 do it. It's up to you. 11 A. (Witness complies.) 12 Q. Doctor, when you were 13 looking at this, you had an opportunity 14 to take a look at this, and you've done a 15 little bit of art here on this. 16 Irrespective of the 17 statistically -- statistical 18 significance, would you agree that, 19 irrespective of design, every one of 20 these studies that -- the vast majority 21 of them, have a point estimate greater 22 than one? 23 MS. MILLER: Objection. 24 THE WITNESS: I mean, the</p>	<p style="text-align: right;">Page 509</p> <p>1 these. 2 And so, therefore, it's hard 3 to know what the true risk ratio is, 4 because if you're consistently 5 overestimating something, just because 6 every study that has the same design that 7 consistently overestimates something, 8 doesn't make the truth. That's something 9 that is estimated. 10 Q. Let me put it this way. 11 Would you agree with me with respect to 12 the cohort studies and the case-control 13 studies, that the vast majority of them 14 have in common a 20 percent -- have 15 20 percent in their confidence interval? 16 MS. MILLER: Objection. 17 THE WITNESS: I don't know 18 why that would be relevant, 19 because as what you were just 20 having me read before, it says 21 look at the risk ratios and see 22 sort of if they're the same. Like 23 the example they gave, they had 24 two risk ratios which were exactly</p>

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<p style="text-align: right;">Page 510</p> <p>1 the same. One was statistically 2 significant, one was not. 3 And as I pointed out in my 4 report, the risk ratios across the 5 case-control studies differ by as 6 much as four times. And so -- 7 BY MR. TISI: 8 Q. Do you really expect in any 9 set of studies in anything that you've 10 ever done, that the risk ratios be 11 exactly the same? 12 A. To be exactly the same? 13 Again, it depends upon the studies that 14 I'm comparing. 15 Q. In fact, wouldn't you be 16 suspicious of a set of studies of any 17 design which had exactly the same risk 18 ratio? 19 MS. MILLER: Objection. 20 THE WITNESS: Again, I would 21 have to see -- it depends on what 22 the studies are that I'm looking 23 at and so forth. 24 BY MR. TISI:</p>	<p style="text-align: right;">Page 512</p> <p>1 this. Because I want to get kind of -- 2 isn't the decision -- the vast majority 3 of these studies have a risk ratio 4 between 1.1 -- irrespective of design, 5 1.1 and 1.5. Would you agree with that? 6 There is some outliers on the low end and 7 outliers on the high end. But the vast 8 majority of them. 9 A. But your -- so your -- 10 your -- your -- 11 Q. Go ahead. 12 A. So when I look at numbers, I 13 can say that those numbers fall in that 14 range. 15 As to whether or not the 16 true risk ratio is in that range, I have 17 no idea, because I know of the biases 18 that exist, especially in the 19 case-control studies. 20 Q. Now, didn't Dr. -- have you 21 calculated a confounding -- how big a 22 confounder would have to be in order to 23 create a risk ratio of 1.3? 24 A. I think it depends. It</p>
<p style="text-align: right;">Page 511</p> <p>1 Q. Have you ever seen that 2 happen, a group of five studies where 3 they all have exact same risk ratio? 4 MS. MILLER: Objection. 5 THE WITNESS: The exact 6 same -- I mean, to how many 7 decimal places? I've seen studies 8 that -- yeah. 9 BY MR. TISI: 10 Q. Where five studies done in 11 different populations, have the exact 12 same risk ratio. 13 MS. MILLER: Objection. 14 BY MR. TISI: 15 Q. You've seen that happen? 16 A. Again, I -- I don't know. I 17 mean, I -- it depends upon what level you 18 are measuring at, is the same. If one 19 would say, oh, look, you know, all these 20 have a risk ratio of one because someone 21 rounded 1.2 down to one, 1.1 down to one, 22 then, yes, that study could have all the 23 same. 24 Q. So, Doctor, let me ask you</p>	<p style="text-align: right;">Page 513</p> <p>1 depends upon many factors. 2 Q. Well, how big would it have 3 to be? 4 A. I can't answer that because 5 I need to know many things in order to 6 calculate that. 7 Q. If you go back to Dr. 8 Rothman's Exhibit Number -- this one, the 9 one that looks like this. 10 MR. SOILEAU: It should be 11 21. 12 BY MR. TISI: 13 Q. 21. 14 A. Yes, I have it. 15 Q. Okay. Here's a section in 16 here, a paragraph on confounding in the 17 case-control studies, on Page 5. 18 Do you see that? 19 A. Yes, I see that paragraph. 20 Q. Okay. Can you read that 21 paragraph? You can read it to yourself. 22 A. You know, I see that -- 23 Q. I just asked you to read it. 24 There's no question pending.</p>

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<p style="text-align: right;">Page 514</p> <p>1 A. Okay. Okay, sorry. Yes, I 2 read that. 3 Q. Okay. Does he not say that, 4 "Family history, ethnicity, obesity and 5 some reproductive risk factors are 6 positively associated with the risk of 7 ovarian cancer"? 8 A. Yes. 9 Q. He says, even if you combine 10 all of those together, they would not 11 explain increased risk? 12 A. You know, he states that 13 there, but I would need to see the 14 calculation. I don't see any 15 calculation. So I don't know if that 16 statement is correct or not. 17 Q. Well, have you done the 18 calculations that would say that -- how 19 big the confounding would have to be in 20 order to explain the consistent risks 21 seen across all these case-control 22 studies? 23 MS. MILLER: Objection. 24 THE WITNESS: I have not</p>	<p style="text-align: right;">Page 516</p> <p>1 get it? 2 THE WITNESS: That would be 3 great. That's the one with the 4 douching? 5 MS. MILLER: Sure. Let's go 6 off the record, and I'll get it. 7 THE VIDEOGRAPHER: The time 8 is 5:09 p.m. Off the record. 9 (Brief pause.) 10 THE VIDEOGRAPHER: The time 11 is 5:11 p.m. Back on the record. 12 BY MR. TISI: 13 Q. Okay. So let me turn to 14 dose-response, which is another area you 15 spend a lot of time on. And I'm going to 16 spend rest of my time on dose-response, 17 which is another of Hill's criteria. 18 First of all, do you agree 19 with me that Bradford Hill said himself 20 that dose-response was not a required 21 finding in order to make a causation 22 assessment, correct? 23 A. I believe Bradford Hill 24 indicates that none of these are -- are a</p>
<p style="text-align: right;">Page 515</p> <p>1 done that calculation, but I don't 2 see a calculation here either. 3 BY MR. TISI: 4 Q. I'm not asking you. He's -- 5 he made his assertion. You're here, I'm 6 getting to ask you questions. You've 7 made a big deal about confounding in your 8 report. A big deal. 9 I'm asking you, have you 10 made any calculation as to how big the 11 confounder would have to be to explain 12 what the meta-analysis show as 13 approximately 1.3 risk associated with 14 ovarian cancer and talc? 15 MS. MILLER: Objection. 16 THE WITNESS: Again, I -- I 17 have not made such a calculation, 18 but -- can I see -- is it the 19 Gonzalez study? 20 BY MR. TISI: 21 Q. Did you bring it with you? 22 MS. MILLER: I've got all 23 the studies in the next room. Do 24 you want to go off the record and</p>	<p style="text-align: right;">Page 517</p> <p>1 requirement to establish causation, and I 2 agree with that. 3 Q. Okay. The next -- the next 4 statement on page -- turn to Page 19 of 5 your report. On Page 19, you say -- and 6 it's your general discussion of 7 dose-response. 8 Do you see that? 9 A. Under biological -- 10 Q. No. Above -- above 11 plausible -- yes, under -- above 12 plausibility. 13 A. Oh, so we're on 19. 14 Q. Yes. 15 A. Okay. 16 Q. You talk about biologic 17 gradient. You start out by saying it's 18 not necessary. And the next -- but the 19 next paragraph is what I'm going to ask 20 you about. 21 A. I dent see where I say it's 22 not necessary. 23 Q. Okay. 24 A. I see that I see if</p>

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<p style="text-align: right;">Page 518</p> <p>1 dose-response is seen, it's more likely 2 the association is causal. 3 Q. Okay. So let's go to the 4 next paragraph. It says, "Regardless of 5 the nature of the dose-response 6 relationship, it needs to be demonstrated 7 consistently across available studies. 8 Specifically the same type of 9 dose-response relationship needs to be 10 exhibited in the different studies. If a 11 threshold relationship is hypothesized, 12 it would require evidence of a threshold 13 value as well, and the value is similar 14 across studies. 15 "If only a few studies 16 exhibit a dose-response rather than all, 17 this criterion" -- "criterion would not 18 be convincingly met." 19 I'm going to have that 20 marked as Exhibit Number 36 (sic). I 21 just pulled that paragraph out. 22 (Document marked for 23 identification as Exhibit 24 Ballman-30.)</p>	<p style="text-align: right;">Page 520</p> <p>1 A. I give citations for that. 2 So you're going to have to bear with me. 3 And I will find -- 4 So 30 and 31. "Hence, 5 observational studies that yield small to 6 modest levels of association require a 7 higher level of supporting evidence to 8 reach a conclusion of causality than do 9 studies with strong levels of 10 association." 11 Q. Okay. So if I look at 30 12 and 31, references to those will be in 13 there? 14 A. That will support that 15 statement. Mm-hmm. 16 Q. Okay. I'll look them up. 17 So now let's go -- let's go 18 to the next -- let's go to exhibit 19 number -- the exhibit that I just gave 20 you, the pull-out of your report. 21 We agreed that, okay -- 22 where is your statement that 23 dose-response needs to be demonstrated 24 consistently across the available</p>
<p style="text-align: right;">Page 519</p> <p>1 BY MR. TISI: 2 Q. First of all, you would 3 agree with me -- would you agree with me 4 that you have not cited a single 5 reference for any of those statements? 6 A. I just think it's common 7 knowledge in terms of the general 8 principles of epidemiology for 9 establishing a dose-response. 10 Q. So where is your -- I'm 11 going to hand you Exhibit Number 30. I'm 12 going ask you about the highlighted ones. 13 Where is your authority 14 for -- in fact, you had indicated that 15 dose-response wasn't even necessary 16 according to Bradford Hill, right? You 17 agreed with that? 18 A. Qualified. I would say -- 19 and I state throughout my report, that if 20 the initial association that's 21 established is weak then it's important 22 that other criteria be met. 23 Q. And where is your basis for 24 that?</p>	<p style="text-align: right;">Page 521</p> <p>1 studies? 2 A. Well, I think I'm sort of 3 explaining what I mean by consistently. 4 I mean, if one study out of 40 had a 5 dose-response, that likely is just due to 6 the fact of multiple comparisons. So 7 that would not establish a dose-response. 8 So dose-response is very 9 similar to establishing whether -- I 10 mean, consistency is sort of implied in 11 terms of dose-response. You can't have 12 one study showing a dose-response out of 13 many and conclude there is a 14 dose-response. 15 Q. Okay. Actually -- I'm 16 actually asking you this. 17 Regardless of the nature of 18 the dose-response, it needs to be 19 demonstrated consistently across the 20 available studies. Where is your support 21 for that statement that it needs to be 22 consistent across all -- across available 23 studies? 24 A. So just -- just common sense</p>

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<p style="text-align: right;">Page 522</p> <p>1 off the top of my head, but I can go  2 through and try to find references if  3 you'd like.  4 But if something is causal,  5 it would be quite odd that it would only  6 have a dose-response in, say, one out of  7 40 studies. And again, I think I  8 explained that in my previous answer.  9 Q. The next sentence says,  10 "Specifically, the same type of  11 dose-response relationship needs to be  12 exhibited in the different studies."  13 Could you -- you have no  14 citation for that, right?  15 A. Again, if something is  16 causal, it would be odd that in one  17 study, it's a threshold effect, and in  18 another study it's a sign effect, and yet  19 in another study it's a decreasing  20 effect, and in another study it's an  21 increasing effect. What would you  22 conclude? How could you conclude it to  23 be causal?  24 Q. Well, it depends on what you</p>	<p style="text-align: right;">Page 524</p> <p>1 nine years .9. Ten to 19 is 1.4.  2 Greater than 20, it's .9.  3 So that's going up and down.  4 Q. Can I stop and ask you that  5 question? Do you know how many people  6 were in the last category?  7 A. No. I have no idea how many  8 people were in the last category. But  9 the width of the confidence intervals  10 there look like it's relatively close to  11 perhaps what's in the previous  12 categories.  13 Q. Okay. Let me ask you  14 another question here. On the next  15 sentence?  16 A. Wait -- I can show you one  17 where -- Whittemore, it goes down. It's  18 1.9, it's 1.6, and greater than ten years  19 it's 1.1.  20 Q. Is that -- is that  21 never/ever? What is that?  22 A. That's duration.  23 Q. Okay. So wouldn't the best  24 measurement be frequency?</p>
<p style="text-align: right;">Page 523</p> <p>1 measure, correct? It depends on the  2 power of the study. It depends upon a  3 lot of things, right?  4 A. Dose-response looks for  5 patterns. I'm not even talking  6 statistically significant here. So  7 things that you just mentioned are  8 talking about statistical significance,  9 which you say people are going to  10 abandoned in the future.  11 I'm talking about looking  12 for evidence that supports a  13 dose-response. And if you have one study  14 that it shows it's going up and down,  15 another study that it's going down,  16 another study that even if it's not  17 statistically significant, that would  18 raise red flags.  19 Q. What study, what study  20 showed that it was going down? Would  21 that be the Huncharek study?  22 A. I can tell you in a minute.  23 Wong? So -- well, here's one that's up  24 and down. So Wong, one point -- one to</p>	<p style="text-align: right;">Page 525</p> <p>1 MS. MILLER: Objection.  2 BY MR. TISI:  3 Q. Or total number -- total  4 number of applications?  5 MS. MILLER: I assume my  6 objection applies to the second  7 question.  8 MR. TISI: Yes, it would.  9 BY MR. TISI:  10 Q. Wouldn't the total --  11 MS. MILLER: That was the  12 second question.  13 BY MR. TISI:  14 Q. Wouldn't --  15 MS. MILLER: Those are two  16 different things.  17 MR. TISI: I got it. I got  18 it.  19 BY MR. TISI:  20 Q. Wouldn't the total --  21 wouldn't the best measure be the total  22 number of applications?  23 A. Well, if we're getting into  24 measurements, first of all, there's no</p>

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<p style="text-align: right;">Page 526</p> <p>1 valid instrument as to how to best 2 measure talc exposure. So having no 3 valid instrument in the first place, I 4 don't think one can say what's the best 5 measure for a dose-response. If 6 something is truly causal and you are 7 measuring increasing dose with some 8 metric that has increasing, so duration 9 would be increasing, that, you know, the 10 longer you use, the more likely you would 11 get ovarian cancer. 12 Frequency would be also a 13 measure of dose-response because using it 14 once a week is, you know, much less than 15 using it every day. And so they are all 16 some measures of dose-response. 17 So if there's a true causal 18 relationship, one would expect seeing 19 consistent sort of dose-responses across 20 any of those measures. 21 Q. And the Terry study did show 22 that, didn't it, when you combine 23 frequency and duration, correct? 24 A. Well, that -- it -- it looks</p>	<p style="text-align: right;">Page 528</p> <p>1 if you do five studies would you expect 2 the same relative risk. 3 And, you know, these all 4 could be sort of the same underlying 5 relative risk and just come up with the 6 variations, because the numbers don't 7 differ that much. So it's sort of a flat 8 relationship. 9 Q. This is -- this is a 10 meta-analysis, isn't it? This is looking 11 at all studies together? 12 A. Yeah, I don't know if that 13 makes it any stronger or not because, 14 again, there's no valid measure that was 15 used. So combining a bunch of studies 16 that use a bunch of different measures 17 together and no valid measure of talc 18 exposure in general, and then no, you 19 know, valid measure as to what the total 20 applications were or consistent 21 standardized measure, you know, it's hard 22 to interpret -- 23 Q. And Penninkilampi -- 24 A. -- the pooled --</p>
<p style="text-align: right;">Page 527</p> <p>1 like -- do we have the Terry study? 2 Q. I'm just asking -- you have 3 the results in your -- in your Table 3. 4 A. Oh, in Table 3. Thank you. 5 Q. Mm-hmm. 6 A. Yeah, I see it now. Thanks. 7 I thought it was here. You know, I -- 8 I -- I actually gave it the benefit of 9 the doubt because there's a couple issues 10 here. One needs to -- so the test for 11 trend is not statistically significant. 12 And if you look at this, you 13 see that it goes from 1.14 to 1.23 down 14 to 1.22 and then up to 1.32. So I don't 15 know if I'd call that a -- 16 Q. So you're kind of quibbling 17 with the Q3 going down from 1.23 to 1.22, 18 as showing, oops, it dropped a tenth of 19 the point? 20 A. Well, I'm quibbling that -- 21 actually if you look at, you know, the 22 last three values there, you know, it 23 well may be the case that there are 24 really -- as you were pointing out, that</p>	<p style="text-align: right;">Page 529</p> <p>1 Q. I'm sorry. I didn't mean to 2 interrupt you. 3 A. Sorry. It's just hard to 4 interpret a pooled study. 5 Q. And Penninkilampi also 6 looked at less than 3,600 applications 7 and more than 3,600 applications, and 8 there was a difference there as well, 9 right? 10 A. And, again, if a test for a 11 trend were done the correct way where you 12 do not have the never category in, it's 13 likely that that would not be a 14 statistically significant difference. 15 But that aside, looking at these point 16 estimates, those again could probably 17 happen -- it doesn't indicate sort of a 18 clear difference between those two 19 numbers -- 20 Q. How about Schildkraut? 21 A. -- and those point 22 estimates. 23 Q. In your study -- in your 24 chart, on the prior page, on Table 1,</p>

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<p style="text-align: right;">Page 530</p> <p>1 Schildkraut shows less than 3,600, had a 2 1.16, and at greater than 3,600 had a 3 1.67, to a P-value of .01. 4 A. That's not really -- that's 5 not really a test for dose-response 6 because there's only two levels. So it's 7 sort of like just comparing two levels to 8 each other. You don't know for certain. 9 Q. So -- so let me go back to 10 your statement. It says Exhibit 11 Number -- exhibit right there, what 12 number -- what exhibit? 13 A. 30. 14 Q. Exhibit 30. Last sentence 15 says, "If only a few studies exhibit 16 dose-response rather than all, the 17 criterion would not be convincingly met." 18 First of all, you have no 19 citation for that either, do you? 20 MS. MILLER: Objection. 21 THE WITNESS: Other than 22 what we discussed before, because 23 if there's true causality, it 24 would be quite odd that only,</p>	<p style="text-align: right;">Page 532</p> <p>1 this criterion more important. 2 And you say that those 3 two -- there's no citation here. But you 4 gave me the citation to that concept 5 earlier, right? 6 A. I did. 7 Q. Okay. The next paragraph 8 says, "To establish a dose-response 9 relationship, the necessary evidence is 10 increasing risk with increasing dose, 11 statistical significance, and 12 consistency. Consistency in this context 13 includes repeated demonstration of the 14 result across different studies, 15 including different study designs and 16 different measures of dose." 17 Do you see that? 18 A. Mm-hmm. 19 Q. And I have that pulled out 20 here as well as Exhibit Number -- 21 (Document marked for 22 identification as Exhibit 23 Ballman-31.) 24 BY MR. TISI:</p>
<p style="text-align: right;">Page 531</p> <p>1 like, two studies show any sort of 2 dose-response relationship and the 3 rest do not. 4 And you know, we can do the 5 counting exercise and go through 6 and see of all these, these 7 different measures of 8 dose-response, how many of them 9 actually are potentially. And I 10 don't even know if I would call 11 the highlighted ones showing a 12 dose-response relationship. 13 BY MR. TISI: 14 Q. Let's go to the next -- Page 15 29 of your report. You say -- on Page 16 29, you say, "Given" -- sorry. Let me 17 see where I find it. Where is the word 18 "given"? Hold on. 19 Oh, okay. On the first 20 paragraph you say -- second sentence, you 21 say, "Given that available data are from 22 observational data and the association is 23 weak, additional evidence is required to 24 rule out a spurious association making</p>	<p style="text-align: right;">Page 533</p> <p>1 Q. As with the prior statement, 2 you don't have a single citation for that 3 do you? 4 A. I think we discussed all 5 this before in Exhibit 30 about why 6 consistency is important. And why the 7 same type of dose-response needs to be 8 important. I think I -- 9 Q. But you didn't cite it 10 there, and you don't cite it here? 11 MS. MILLER: Objection. 12 BY MR. TISI: 13 Q. You didn't cite it in the 14 prior exhibit, and you don't cite 15 anything here. 16 MS. MILLER: Sorry. I 17 thought the last thing was a 18 question, so I objected to that. 19 But this is a new question. I 20 object to this one as well. 21 BY MR. TISI: 22 Q. Yeah. Okay. We looked at 23 two -- 24 A. Yeah, yeah, yeah, yeah.</p>

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<p style="text-align: right;">Page 534</p> <p>1 Q. -- Exhibit Number 30, and 2 Exhibit Number 31. They're both the same 3 statement about consistency, and you 4 don't have a citation for either one of 5 those? 6 A. And I explained why there is 7 no citation is, again, that if there is a 8 causal relationship that is in fact true, 9 one would expect to see the same type of 10 relationship because if it goes up in one 11 study, down in another, up and down, or 12 stays flat, it's hard to understand how 13 something that truly has a causal effect 14 would come up with these different sort 15 of dose-responses. 16 And again, consistency is, 17 again, that you don't have these 18 different patterns going on in the data. 19 Q. But you have no citation for 20 that whatsoever, and the meta-analyses 21 that were done, the two of them that 22 looked at it, whether it be Terry -- or 23 you pointed out. I'm blanking on the 24 other one. Both showed evident of a</p>	<p style="text-align: right;">Page 536</p> <p>1 even know if there's any valid measure of 2 that. 3 Q. But you would agree with me 4 that both of these are peer-reviewed 5 studies, and when you looked at the total 6 number of applications, which is a 7 measure of dose, we saw an increased 8 risk. Whether you think it's the right 9 inference or not is fine, but you agree 10 with that -- that that's what they 11 showed, both Penninkilampi and Terry. 12 And that's on Page 34 of your report. 13 A. I don't think I said that. 14 I think I said Penninkilampi, you can't 15 even infer dose-response because there's 16 only two doses. It's only two lines. So 17 you can't -- I mean, only like -- you 18 know, dichotomous things. 19 So one can't really infer a 20 dose-response, and it's not even clear 21 that those two numbers in reality differ 22 from each other because we had this 23 discussion about, you know, point 24 estimates, you know, not having -- that</p>
<p style="text-align: right;">Page 535</p> <p>1 dose-response -- Terry and 2 Penninkilampi -- that looked at total 3 number of -- those are the only two that 4 looked at the total number of 5 applications, and they both showed 6 increasing dose -- increasing risk with 7 increasing number of applications, true? 8 A. That is -- again, there's no 9 evidence that that's the right metric 10 because there's no validated instrument 11 for measuring talc in the first place. 12 And so it's sort of cherry-picking to 13 say, oh, okay, that one shows it but a 14 measure of frequency doesn't show it, a 15 measure of duration doesn't show it, even 16 within the same studies. 17 And so I think most 18 reasonable people would say, if there 19 really is a dose-response, why does it 20 have to be sort of the total lifetime 21 applications, but I'm not seeing it in 22 the total of years, which goes into that 23 calculation, nor the frequency, which 24 goes into that calculation. And I don't</p>	<p style="text-align: right;">Page 537</p> <p>1 they don't have to be the same, and if 2 they are pretty close to each other, who 3 knows. 4 So that's the same with the 5 Terry study too. So I do not agree. 6 Q. Okay. But different -- you 7 know that in those studies, that both of 8 them, they noted an evidence of 9 dose-response, correct? 10 MS. MILLER: Objection. 11 THE WITNESS: I would have 12 to see the studies and see exactly 13 how they stated their conclusions. 14 Can you -- 15 BY MR. TISI: 16 Q. I'm just -- I'm just asking 17 you, do you recall that that was the 18 case? 19 A. Off the -- 20 MS. MILLER: Objection. 21 MR. LOCKE: Objection. 22 BY MR. TISI: 23 Q. I'm asking you, do you 24 recall or not? If you don't recall,</p>

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<p style="text-align: right;">Page 538</p> <p>1 that's fine.  2 A. Off the top of my head, I do  3 not recall.  4 Q. Okay. I want to ask you a  5 couple questions about meta-analysis and  6 kind of move on from there.  7 First of all, not all  8 dose-responses are monotonic, are they?  9 MS. MILLER: Objection.  10 THE WITNESS: I believe --  11 there can be different type of  12 dose-responses.  13 BY MR. TISI:  14 Q. Okay. Have you considered  15 that?  16 A. In what sense?  17 Q. Have you considered it at  18 all?  19 MS. MILLER: Objection.  20 THE WITNESS: I think I --  21 just in -- I mean, in what sense?  22 BY MR. TISI:  23 Q. In connection with  24 dose-response?</p>	<p style="text-align: right;">Page 540</p> <p>1 BY MR. TISI:  2 Q. In any of the studies.  3 A. Well, I know it looks like  4 Terry did a test for trend that does not  5 include the never/none category. And  6 it's P-value is .17. So -- and that is a  7 flat relationship.  8 Checking to see.  9 So Cramer 1999 did the  10 correct test. He did a trend test. And  11 his P-value of .48 and .16, that's a  12 trend test that does not include the  13 never category.  14 Q. Right, but when he looked at  15 the total number of applications, you saw  16 an increase that went from 1.1 to 1.38,  17 went down to 1.36, and up to 1.49.  18 A. I think we're talking about  19 the different Cramer. Sorry.  20 Q. Cramer 2016?  21 A. No. I was looking -- I said  22 Cramer 1999. I'm sorry.  23 Q. I'm looking --  24 A. I misspoke that.</p>
<p style="text-align: right;">Page 539</p> <p>1 A. Well, in cancer it would be  2 very rare -- in a non-monotonic, one  3 would be that the higher the dose, the  4 less the risk. It could be concave. I  5 mean, that would be quite --  6 Q. Could it --  7 A. -- bizarre different from  8 any other cancers I've seen.  9 Q. Have you ever heard  10 depletion of the susceptibles?  11 A. No, I have not.  12 Q. Okay. That as people die,  13 they're not going to be showing a --  14 anyway. I'll move on.  15 What about a trend test  16 when -- when the trend test was used in  17 non-users, did they show a dose-response?  18 MS. MILLER: Objection.  19 BY MR. TISI:  20 Q. When a trend test was used,  21 did it show a dose-response?  22 MS. MILLER: Well, where?  23 THE WITNESS: Trend test  24 used where, meaning what?</p>	<p style="text-align: right;">Page 541</p> <p>1 You asked me which ones did  2 the correct trend test. And I'm saying  3 Cramer 1999.  4 Q. What about Cramer 2016?  5 MS. MILLER: You didn't  6 misspeak. You said 1999.  7 BY MR. TISI:  8 Q. What about Cramer 2016?  9 A. That one does -- that test  10 for trend includes the never versus none  11 category.  12 Q. All right. Okay. Let me  13 ask you a couple questions about -- about  14 meta-analyses.  15 We've been talking about the  16 individual studies. Is it your view  17 that -- you know, you mentioned several  18 times.  19 MR. TISI: I'm sorry. I'm  20 sorry. You reached over. You  21 reached over that time.  22 MS. MILLER: I'm moving  23 back.  24 MR. TISI: You reached over</p>

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<p style="text-align: right;">Page 542</p> <p>1 that time.</p> <p>2 MS. MILLER: I'm so sorry.</p> <p>3 MR. TISI: And you kicked</p> <p>4 me.</p> <p>5 MS. MILLER: I'm so sorry.</p> <p>6 MR. TISI: And I don't take</p> <p>7 it personally.</p> <p>8 MS. SHARKO: Can I do that</p> <p>9 too.</p> <p>10 MS. MILLER: I had to</p> <p>11 stretch my legs. It's been a very</p> <p>12 long day. I can only stretch that</p> <p>13 far.</p> <p>14 BY MR. TISI:</p> <p>15 Q. Doctor, you mentioned</p> <p>16 several times that a certain number of</p> <p>17 case-control studies found a</p> <p>18 statistically significant result, and a</p> <p>19 certain found -- didn't. And then a</p> <p>20 certain number of case -- cohort studies</p> <p>21 did not find a statistically significant</p> <p>22 result.</p> <p>23 Do you remember that kind of</p> <p>24 general testimony?</p>	<p style="text-align: right;">Page 544</p> <p>1 not.</p> <p>2 Looking at the cohort</p> <p>3 studies, none of them found a</p> <p>4 statistically significant</p> <p>5 association.</p> <p>6 And the magnitude of the</p> <p>7 risk ratios for these groups of</p> <p>8 studies also vary.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Would you agree with me that</p> <p>11 it is wrong to simply count the number</p> <p>12 of -- count the number of studies and</p> <p>13 kind of do it like a democracy. There</p> <p>14 are a certain number of studies that say</p> <p>15 X that's not statistically significant.</p> <p>16 Certain number that say Y, they are, and</p> <p>17 the non-statistical numbers win?</p> <p>18 A. It depends.</p> <p>19 Q. Okay. Do you ever do that?</p> <p>20 A. It depends. I mean, again,</p> <p>21 I -- it depends upon many things.</p> <p>22 You know, if I have, like,</p> <p>23 you know, randomized controlled trials,</p> <p>24 you know, and, you know, all of them show</p>
<p style="text-align: right;">Page 543</p> <p>1 MS. MILLER: Objection.</p> <p>2 BY MR. TISI:</p> <p>3 Q. Yeah, I mean. Yes?</p> <p>4 A. What's your question?</p> <p>5 Q. My question is do you</p> <p>6 remember that testimony. I'm kind of</p> <p>7 referring you. Remember you listed,</p> <p>8 well, you know, you kind of looked at</p> <p>9 them together. And some were</p> <p>10 statistically significant, some weren't.</p> <p>11 Some were in case-control, some were in</p> <p>12 cohort. Do you remember that testimony?</p> <p>13 MS. MILLER: Objection.</p> <p>14 MR. TISI: You can object.</p> <p>15 THE WITNESS: So what I --</p> <p>16 what I -- I recall sort of when</p> <p>17 looking at the evidence in</p> <p>18 totality is that you know, the --</p> <p>19 the hospital-based controls did</p> <p>20 not find statistical significance.</p> <p>21 The population-based</p> <p>22 controlled studies -- case-control</p> <p>23 studies, some found a statistical</p> <p>24 significant association, some did</p>	<p style="text-align: right;">Page 545</p> <p>1 an effect, and then or none of them show</p> <p>2 an effect, let's say. So I have</p> <p>3 randomized control trials --</p> <p>4 Q. But that's not what we're</p> <p>5 talking about. We're not talking about</p> <p>6 randomized controlled.</p> <p>7 Let's just talk about, for</p> <p>8 example, in the case-control studies.</p> <p>9 A. You asked me if there are</p> <p>10 any situations, and I was trying to</p> <p>11 answer that.</p> <p>12 Q. And we're not talking about</p> <p>13 that. And I apologize, because we're</p> <p>14 talking about in the context of this</p> <p>15 case. There are no randomized control</p> <p>16 trials because it would be unethical to</p> <p>17 do so, correct?</p> <p>18 MS. MILLER: Objection.</p> <p>19 THE WITNESS: Again, I</p> <p>20 talked about reasons why, you</p> <p>21 know, randomized control studies</p> <p>22 are not done and, you know --</p> <p>23 yeah, so anyway.</p> <p>24 BY MR. TISI:</p>

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<p>1 Q. They could not be done here 2 because you can't test somebody -- 3 assuming you can even design such a 4 study, you couldn't -- with the 5 hypothesis being, let's expose people to 6 something and see whether it causes 7 cancer? 8 MS. MILLER: Objection. 9 BY MR. TISI: 10 Q. It would be unethical to do 11 that, right? 12 A. Yeah. I mean, just in 13 general, one would not do a clinical 14 trial and say, okay, we're going to 15 expose people to something that there's 16 evidence for that it's harmful, but I 17 don't know if it applies in this case. 18 It's been purported that the 19 use of talc is harmful. But I don't know 20 if there is -- 21 Q. Would you ever participate 22 in a study that would test the hypothesis 23 that talc would cause ovarian cancer? 24 MS. MILLER: Objection.</p>	<p>1 done, and the intent for 2 meta-analyses is that the 3 randomized controlled trials, back 4 when trials were starting to 5 become popular, were too small on 6 their own to have statistical 7 significance. 8 So the idea was there were 9 several trials done in the same 10 disease, essentially, of the same 11 treatments, and so to get the 12 necessary power in order to make a 13 definitive statement, 14 meta-analyses were used. 15 MR. TISI: Okay. 16 (Document marked for 17 identification as Exhibit 18 Ballman-32.) 19 BY MR. TISI: 20 Q. Let me show you a textbook, 21 a chapter of a textbook called 22 "Introduction to Meta-Analyses" by 23 Borenstein. Is that something that 24 you've ever seen before?</p>
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<p>1 BY MR. TISI: 2 Q. A clinical trial? 3 MS. MILLER: Objection. 4 THE WITNESS: Again, I don't 5 think people would do such a 6 clinical trial -- 7 BY MR. TISI: 8 Q. And you wouldn't -- 9 A. -- with that question. 10 I mean, I would participate 11 in one if it says talc would prevent sort 12 of this from happening because I would 13 see a benefit. I wouldn't participate in 14 a trial where there's no benefit being 15 hypothesized. 16 Q. So now the question is, why 17 do we do meta-analysis? Why do we do 18 meta-analysis? 19 MS. MILLER: Objection. 20 THE WITNESS: Well, 21 meta-analysis, and the history of 22 meta-analysis are that they were 23 first used for randomized 24 controlled trials. And they were</p>	<p>1 A. I haven't seen this 2 particular textbook. 3 Q. I'm marking it as Exhibit 4 Number 32? And I pulled out -- 5 MS. MILLER: Is this Xerox 6 on cardboard? 7 MR. TISI: I know. The 8 machine, it was weird. It was the 9 FedEx office. 10 BY MR. TISI: 11 Q. Chapter 28 is called "Vote 12 Counting, a New Name For an Old Problem." 13 Do you see that? 14 A. I'm sorry. What page are we 15 on? 16 Q. It's chapter 28. If you go 17 in, there's the chapter there? 18 A. Oh, I see. It says "Vote 19 Counting, a New Name For an Old Problem." 20 Yes. 21 Q. So just -- you would agree 22 with me just looking at the number of 23 studies that show statistically 24 significant results and the numbers that</p>

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<p style="text-align: right;">Page 550</p> <p>1 don't is not a good scientific 2 methodology, correct? 3 A. Again, it depends. 4 Q. Well, at the very end of in 5 statement -- and I guess that was a 6 pretty non-controversial thing, at least 7 I thought it was. At the very end, 8 there's a box that says "Summary Points" 9 on Page 255. 10 I'm going to ask you if this 11 is true. "Vote counting" -- and by vote 12 counting, I mean counting the number of 13 positive and negative studies. "Vote 14 counting is the process of counting the 15 number of studies that are not (sic) 16 statistically significant and comparing 17 those with the number that are not 18 statistically significant." 19 Do you see that? 20 A. Yes, I see what you read. 21 Q. And it says, "Vote counting 22 treats a nonsignificant P-value as 23 evidence that an effect is absent. In 24 fact, though small, moderate, and even</p>	<p style="text-align: right;">Page 552</p> <p>1 studies being combined -- again, as I 2 mentioned the intent of a meta-analyses 3 was for randomized clinical trials. And 4 it was to combine small, underpowered 5 studies together in order to get 6 sufficient power. 7 Q. Do you agree that it is 8 appropriate to use meta-analysis to 9 combine observational studies, even 10 observational studies of different 11 design? 12 A. No. I think it is incorrect 13 to do a meta-analyses to combine 14 observational studies, especially 15 observational studies of different 16 designs. 17 Q. Yet in the talc area, you 18 know of at least four, five or six 19 meta-analyses that have been done that 20 have done exactly that, that have passed 21 peer review, correct? 22 A. Yeah, and I hope ASA comes 23 out with a statement on that, because the 24 intent of meta-analyses was not to</p>
<p style="text-align: right;">Page 551</p> <p>1 large effects may yield nonsignificant 2 P-values due to inadequate statistical 3 power. Therefore, vote counting is never 4 a valid approach." 5 A. Yes, I see that -- that 6 stated there. 7 Q. Do you agree that vote 8 counting -- in other words, counting the 9 number of studies that are not 10 statistically significant and comparing 11 them with the numbers that are, is never 12 a valid approach? 13 A. Again, I said it depends. 14 So if all the studies were of the same 15 sample size done in the same population 16 using the same treatment, and all of them 17 were adequately powered, and, like, two 18 only found a statistically significant 19 result, and the rest did not, I think 20 that's evidence right there that there 21 really is no effect. 22 Q. And that -- that's why we do 23 meta-analyses, correct? 24 A. We do meta-analyses when the</p>	<p style="text-align: right;">Page 553</p> <p>1 combine observational studies. And 2 that's why in the meta-analyses, in that 3 chart of increasing evidence that I -- 4 I -- we had discussed previously in my 5 report, the meta-analyses at the top are 6 meta-analyses of randomized trials. I've 7 never seen any pyramid of evidence of 8 that that puts in meta-analyses of 9 observational studies anywhere in that 10 pyramid because it's unknown. 11 Q. But I'm -- let me just get 12 it down. There are six meta-analyses in 13 this -- in this litigation, five which 14 have been published, one of which is 15 being submitted to peer review, right, 16 the Taher study. 17 A. Yes, correct. 18 Q. And there's -- there's six 19 altogether, five of which are 20 published -- 21 A. Oh, wait? Six altogether. 22 No, I'm sorry. Go through the numbers 23 again. My count is seven published. 24 Q. Okay. Fine.</p>

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<p>1 A. And -- okay.</p> <p>2 Q. Fine. Whatever the number</p> <p>3 happens to be, it happens to be. I'm</p> <p>4 doing it off the top of my head.</p> <p>5 Are you saying that because</p> <p>6 all of those studies combined</p> <p>7 observational studies -- let's just deal</p> <p>8 with that issue -- that that was</p> <p>9 unscientific, and they should not have</p> <p>10 passed peer review?</p> <p>11 A. I am saying that they're</p> <p>12 good for hypothesis generating, and</p> <p>13 that's about it. They are not good for</p> <p>14 making definitive statements with respect</p> <p>15 to things such as causality or whether</p> <p>16 there truly is an association.</p> <p>17 Q. Do you think that those</p> <p>18 should have passed peer review. If you</p> <p>19 were peer reviewers on any of the</p> <p>20 meta-analyses that are in this case,</p> <p>21 would you have given a green light to</p> <p>22 allow those to be published?</p> <p>23 MS. MILLER: Objection.</p> <p>24 THE WITNESS: Again, they</p>	<p>1 meta-analyses of observational</p> <p>2 data.</p> <p>3 BY MR. TISI:</p> <p>4 Q. Okay. And you think it</p> <p>5 would be inappropriate to rely on that</p> <p>6 data for consideration in the -- of the</p> <p>7 Bradford Hill criteria for causation in</p> <p>8 talc and ovarian cancer?</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: As I said,</p> <p>11 meta-analyses are good for</p> <p>12 hypothesis generating, but they</p> <p>13 are not sufficient evidence to --</p> <p>14 to make a definitive statement</p> <p>15 about causation.</p> <p>16 BY MR. TISI:</p> <p>17 Q. I didn't ask about</p> <p>18 definitive statements. I'm asking, are</p> <p>19 they even appropriate to consider in a</p> <p>20 Bradford Hill analysis, or is that a</p> <p>21 methodologic flaw if anybody were to</p> <p>22 consider a meta-analysis in the context</p> <p>23 of doing a Bradford Hill test or analysis</p> <p>24 for ovarian cancer and talc?</p>
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<p>1 are good for hypothesis</p> <p>2 generating. And I didn't say that</p> <p>3 hypothesis generating is not --</p> <p>4 not good -- or is not -- I'm</p> <p>5 getting tired. I'm searching for</p> <p>6 words here.</p> <p>7 I did not say that</p> <p>8 hypothesis generating should not</p> <p>9 be published.</p> <p>10 BY MR. TISI:</p> <p>11 Q. You would agree with me that</p> <p>12 people disagree with you on the value of</p> <p>13 meta-analyses, correct?</p> <p>14 MS. MILLER: Objection.</p> <p>15 THE WITNESS: Well, I -- I</p> <p>16 don't know. All I know is JCO,</p> <p>17 the journal I'm deputy editor for,</p> <p>18 which has quite a high impact</p> <p>19 factor, we would never, ever</p> <p>20 publish a meta-analyses -- well, I</p> <p>21 shouldn't say that. That's too</p> <p>22 strong.</p> <p>23 It would be very rare that</p> <p>24 we ever would publish a</p>	<p>1 MS. MILLER: Objection.</p> <p>2 THE WITNESS: As I -- I do</p> <p>3 cite one of the articles here that</p> <p>4 says -- I don't -- within Bradford</p> <p>5 Hill, it says look at the totality</p> <p>6 of the data. But it's more</p> <p>7 important to look at the</p> <p>8 individual studies and see what</p> <p>9 the conclusion comes from there,</p> <p>10 rather than a meta-analyses.</p> <p>11 So I'm not sure how a</p> <p>12 meta-analyses sort of plays into</p> <p>13 the Bradford Hill except coming up</p> <p>14 with some summary values.</p> <p>15 BY MR. TISI:</p> <p>16 Q. But you do know that most</p> <p>17 people looking at this question have</p> <p>18 looked at -- at the meta-analyses,</p> <p>19 correct, in connection -- I mean, Health</p> <p>20 Canada did, correct? Are they wrong for</p> <p>21 having done so?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: I didn't say</p> <p>24 that. I mean, I said even I've</p>

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<p>1 looked at the meta-analyses 2 because that's the totality of the 3 data, to see if there's any sort 4 of additional information that it 5 brings forward. 6 BY MR. TISI: 7 Q. But do you remember the 8 statement -- and I pulled it out there. 9 I think it was Exhibit Number 5. That 10 statement says that they found a 11 consistent result across meta-analyses 12 and additional evidence is consistent 13 with causation. 14 MS. MILLER: Who is "they"? 15 MR. TISI: Health Canada. 16 THE WITNESS: I'm trying to 17 find Exhibit 5. 18 MR. LOCKE: Can I ask for a 19 time check? 20 MR. TISI: We've got about 21 four minutes. 22 THE WITNESS: I'm looking 23 for Exhibit 5. Do you have it 24 handy? Oh, I got it. I got it.</p>	<p>1 MS. MILLER: Objection. 2 THE WITNESS: And I said 3 that when one is doing a proper 4 sort of causal analyses that's 5 based upon, you know, established 6 epidemiology principles, one looks 7 at all studies, including 8 meta-analyses. 9 BY MR. TISI: 10 Q. Are they wrong for having 11 relied on them? Having looked at them, 12 can they rely on them? 13 MS. MILLER: Objection. 14 THE WITNESS: I'm not sure 15 if they relied on them from this 16 statement here. I can't tell that 17 they relied just on meta-analyses 18 or not. 19 BY MR. TISI: 20 Q. What is the journal JCO? 21 A. The Journal of Clinical 22 Oncology. 23 Q. One final question. You 24 made a comment in the Taher study that</p>
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<p>1 I got it. Okay. 2 BY MR. TISI: 3 Q. Were they wrong -- were 4 Health Canada wrong in Exhibit 5 for 5 relying on that? 6 A. So I think I said that 7 meta-analyses, it's not surprising that 8 they are consistent because they are 9 analyzing the same set of data, and so 10 one would expect -- 11 Q. I didn't ask you that. I 12 didn't ask you about consistency. I'm 13 asking were they wrong for even 14 considering them? 15 A. But that's a different 16 question -- 17 Q. It is a different question. 18 A. -- than what you just asked 19 me there. 20 Q. I'm asking you, are they 21 wrong for having considered them in the 22 context of looking at the causal 23 inference for talcum powder and ovarian 24 cancer?</p>	<p>1 they indicated that they thought it was a 2 possible association. And you said that 3 you thought that as a peer reviewer, they 4 would take that out? 5 A. No. They said a possible 6 causal -- 7 Q. Causal association. 8 A. -- association. 9 Q. And you would take -- you 10 thought that that was something that 11 would be taken out by peer reviewers, 12 correct? 13 A. Of -- of high quality 14 journals, yes. 15 Q. And you -- but that's pure 16 speculation on your part, right? 17 A. No, I do not believe so. 18 Through all my experience in the numerous 19 papers that I've reviewed and -- both for 20 JCO and as a reviewer of other things, 21 that's pushing the data, because one 22 assumes no causal relationship, and you 23 need evidence for it before you can state 24 causality.</p>

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<p style="text-align: right;">Page 562</p> <p>1 Q. Would it surprise you to 2 know that we have meta-analyses in JCO, 3 correct? Would that surprise you? You 4 mentioned that you've never published 5 meta-analyses or rarely. Would that 6 surprise you? 7 A. There are meta-analyses -- 8 MS. MILLER: Objection. She 9 said meta-analyses -- objection. 10 THE WITNESS: There are 11 meta-analyses in JCO of randomized 12 clinical trials. And in fact, one 13 of the studies you showed me today 14 was a meta-analysis. It was a 15 pooled analysis, of individual 16 patient-level data. 17 BY MR. TISI: 18 Q. Okay. So is it your 19 statement that JCO would not publish a 20 meta-analyses -- meta-analysis of 21 observational data? 22 MS. MILLER: Objection. 23 Misstates -- 24 THE WITNESS: I said it</p>	<p style="text-align: right;">Page 564</p> <p>1 minute. 2 MR. TISI: I'm totally okay. 3 I'll give you -- I'll give you my 4 minute. 5 Thank you very much. I have 6 no further questions. 7 MS. MILLER: I just have a 8 few questions for you, Dr. 9 Ballman. 10 - - - 11 EXAMINATION 12 - - - 13 BY MS. MILLER: 14 Q. Can you please turn back to 15 Exhibit Number 25. 16 MR. TISI: Which is what? 17 THE WITNESS: The National 18 Cancer Institute one. This one? 19 BY MS. MILLER: 20 Q. Can you tell me what the 21 title of that exhibit is? 22 A. The title is "Ovarian, 23 Fallopian Tube, and Primary Peritoneal 24 Cancer" -- I don't know if there's</p>
<p style="text-align: right;">Page 563</p> <p>1 was -- 2 MS. MILLER: 3 Mischaracterizes her testimony. 4 Please let me finish my 5 objection, even though you're 6 eager to talk. 7 BY MR. TISI: 8 Q. You can answer the question. 9 A. Okay. So I said that it 10 would very rarely happen. I had 11 corrected. I had said never, but I said, 12 no, wait a minute, it would very rarely 13 happen. 14 Q. Okay. So -- so you would 15 agree with me that there have been 16 observational meta-analyses in JCO? 17 A. I have no idea if there have 18 been or not. I cannot say that off the 19 top of my head. 20 MR. TISI: I don't think I 21 have any questions. I think I'm 22 down to the -- 23 MS. MILLER: You have one 24 minute. Go crazy with your last</p>	<p style="text-align: right;">Page 565</p> <p>1 anything under the sticker -- 2 "Prevention, Health Professional 3 Version." 4 Q. And what is this document? 5 A. It's a document that was 6 published by the National Cancer 7 Institute that's talking about who's at 8 risk for ovarian cancer and established 9 risk factors of ovarian cancer, I 10 believe, as best I can tell. 11 Q. Please turn to Page 11. 12 A. Yes, I'm there. 13 Q. Do you see the subheading 14 titled "Perineal Talc Exposure"? 15 A. Oh, yes, I see "Perineal 16 Talc Exposure." Yes. 17 Q. Can you please read the 18 sentence under that? 19 A. "The weight" -- 20 Q. You did a lot of reading 21 today. I thought we should you read, 22 too. 23 A. "The weight of evidence does 24 not support an association between</p>

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<p style="text-align: right;">Page 566</p> <p>1 perineal talc exposure and an increased 2 risk of ovarian cancer." 3 Q. Did Mr. Tisi read this 4 sentence to you? 5 A. No. And it goes on to say 6 that the result from case-control and 7 cohort studies are inconsistent. 8 MS. MILLER: I have no 9 further questions. 10 MR. TISI: I have a 11 question. I'll use my minute and 12 add a couple minutes to yours. 13 MS. MILLER: Wait. I used 14 30 seconds. So you have a minute 15 and 30 seconds. 16 MR. TISI: Okay. Well don't 17 waste my 30 seconds. I don't 18 think I'll use 30 seconds. 19 - - - 20 EXAMINATION 21 - - - 22 BY MR. TISI: 23 Q. In that section, it 24 refers -- there are four footnotes under</p>	<p style="text-align: right;">Page 568</p> <p>1 references for the values that 2 they're reporting before the 3 reference -- 4 BY MR. TISI: 5 Q. So if you go to the back -- 6 A. -- such as, "However, a 7 dose-response relationship was not 8 found," which is reference 42. 9 Q. Can you look at Page 16 of 10 18. 11 MS. SHARKO: I really think 12 your time is up at this point. 13 MS. MILLER: Yeah, your time 14 is way up. 15 THE WITNESS: I'm there. 16 MS. MILLER: You've just 17 gone over two more minutes. 18 MR. TISI: Counsel, you've 19 been wasting my time. I'm going 20 to ask this question. And if you 21 want to -- you want to walk out, 22 that's fine. I'll ask the judge 23 for the time. 24 BY MR. TISI:</p>
<p style="text-align: right;">Page 567</p> <p>1 the perineal talc section. 2 Do you see that? 3 A. Yeah, I'm sorry. I thought 4 I was done. 5 Q. On -- on Page 12. Footnote 6 43 through footnote 46. 7 Do you see that? 8 A. I see -- I see Reference 42 9 and I see a reference 43. I don't see 10 where you see -- oh, there's 44. Yeah, I 11 see -- I see a bunch of -- 12 Q. And 46? 13 A. 44, 45, 46. 14 Q. Right. So there are five 15 references in this paragraph, correct? 16 A. Yes. 17 Q. Okay. And so we can assume, 18 can we not, that those are the references 19 they looked at? 20 MS. MILLER: Objection. 21 Calls for speculation. 22 THE WITNESS: I don't know 23 if it's all the references that 24 they looked at. I think they are</p>	<p style="text-align: right;">Page 569</p> <p>1 Q. How many -- how many 2 references -- of all these references, 3 there are five references. Do you have 4 any -- any suggestion that the NCI 5 actually did a causation analysis like 6 you or Health Canada or the plaintiffs' 7 experts or anybody else did? 8 MS. MILLER: Objection. 9 THE WITNESS: I don't know. 10 I don't know what they did. 11 MR. TISI: Thank you very 12 much. 13 THE VIDEOGRAPHER: Stand by, 14 please. Remove your microphones. 15 The time is 5:54 p.m. This 16 completes today's deposition. 17 (Excused.) 18 (Deposition concluded at 19 approximately 5:54 p.m.) 20 21 22 23 24</p>

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<p style="text-align: right;">Page 570</p> <p>1</p> <p>2 CERTIFICATE</p> <p>3</p> <p>4</p> <p>5 I HEREBY CERTIFY that the</p> <p>6 witness was duly sworn by me and that the</p> <p>7 deposition is a true record of the</p> <p>8 testimony given by the witness.</p> <p>9</p> <p>10 It was requested before</p> <p>11 completion of the deposition that the</p> <p>12 witness, KARLA BALLMAN, Ph.D., have the</p> <p>13 opportunity to read and sign the</p> <p>14 deposition transcript.</p> <p>15</p> <p>16 _____</p> <p>17 MICHELLE L. GRAY,</p> <p>18 A Registered Professional</p> <p>19 Reporter, Certified Shorthand</p> <p>20 Reporter, Certified Realtime</p> <p>21 Reporter and Notary Public</p> <p>22 Dated: March 24, 2019</p> <p>23</p> <p>24 (The foregoing certification</p> <p>of this transcript does not apply to any</p> <p>reproduction of the same by any means,</p> <p>unless under the direct control and/or</p> <p>supervision of the certifying reporter.)</p>	<p style="text-align: right;">Page 572</p> <p>1 - - - - -</p> <p>2 E R R A T A</p> <p>3 - - - - -</p> <p>4 PAGE LINE CHANGE</p> <p>5 _____</p> <p>6 REASON: _____</p> <p>7 _____</p> <p>8 REASON: _____</p> <p>9 _____</p> <p>10 REASON: _____</p> <p>11 _____</p> <p>12 REASON: _____</p> <p>13 _____</p> <p>14 REASON: _____</p> <p>15 _____</p> <p>16 REASON: _____</p> <p>17 _____</p> <p>18 REASON: _____</p> <p>19 _____</p> <p>20 REASON: _____</p> <p>21 _____</p> <p>22 REASON: _____</p> <p>23 _____</p> <p>24 REASON: _____</p>
<p style="text-align: right;">Page 571</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition</p> <p>4 over carefully and make any necessary</p> <p>5 corrections. You should state the reason</p> <p>6 in the appropriate space on the errata</p> <p>7 sheet for any corrections that are made.</p> <p>8 After doing so, please sign</p> <p>9 the errata sheet and date it.</p> <p>10 You are signing same subject</p> <p>11 to the changes you have noted on the</p> <p>12 errata sheet, which will be attached to</p> <p>13 your deposition.</p> <p>14 It is imperative that you</p> <p>15 return the original errata sheet to the</p> <p>16 deposing attorney within thirty (30) days</p> <p>17 of receipt of the deposition transcript</p> <p>18 by you. If you fail to do so, the</p> <p>19 deposition transcript may be deemed to be</p> <p>20 accurate and may be used in court.</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 573</p> <p>1</p> <p>2 ACKNOWLEDGMENT OF DEPONENT</p> <p>3</p> <p>4 I, _____, do</p> <p>5 hereby certify that I have read the</p> <p>6 foregoing pages, 1 - 574, and that the</p> <p>7 same is a correct transcription of the</p> <p>8 answers given by me to the questions</p> <p>9 therein propounded, except for the</p> <p>10 corrections or changes in form or</p> <p>11 substance, if any, noted in the attached</p> <p>12 Errata Sheet.</p> <p>13</p> <p>14</p> <p>15 _____</p> <p>16 KARLA BALLMAN, Ph.D. DATE</p> <p>17</p> <p>18</p> <p>19 Subscribed and sworn</p> <p>20 to before me this</p> <p>21 _____ day of _____, 20____.</p> <p>22 My commission expires: _____</p> <p>23</p> <p>24 _____</p> <p>Notary Public</p>

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<b>1:00</b> 271:16	<b>12:49</b> 281:1	<b>1960s</b> 62:24	<b>200</b> 53:4 183:23 265:7	<b>215</b> 3:14
<b>1:27</b> 281:9	<b>13</b> 5:6,15 245:17	<b>1965</b> 95:11 145:21	<b>200,000</b> 368:9 370:7 371:2 372:5 384:12 385:11	<b>216</b> 3:19
<b>10</b> 187:18 188:16 194:15 248:6 456:5	<b>130</b> 2:13	<b>1982</b> 55:6,13 56:3,12 92:19	<b>2000</b> 3:13 184:8 338:13 340:6	<b>22</b>
<b>10A</b> 188:21	<b>131</b> 476:2	<b>199</b> 7:9	<b>20004</b> 4:4	
<b>10-B</b> 189:23	<b>14</b> 247:20	<b>1999</b> 540:9,22 541:3,6	<b>20005</b> 3:4	
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<b>10-E</b> 199:1	<b>1440</b> 3:3			
<b>10:10</b> 104:7	<b>145</b> 6:9			
<b>10:25</b> 104:11	<b>15</b>			



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<b>78,000</b>	<b>988-2706</b>			
384:17	3:14			
<b>8</b>				

# Exhibit 5

**Invoice**

Dr. Karla Ballman

**Statistician and Consultant**

430 East 63<sup>rd</sup> Street, Apt. 12G

New York, NY 10065

507-301-3013

[kab2053@med.cornell.edu](mailto:kab2053@med.cornell.edu)

Please remit payment to Karla Ballman at the address above.

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Invoice Date: 03/07/2019

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Consulting Services for Johnson and Johnson Talcum Powder and ovarian cancer litigation: 11/12/2018-03/07/2019

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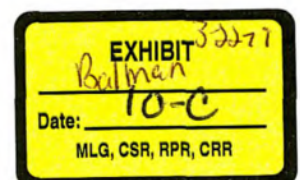
Consulting Services/Fees

Description	Hours
[REDACTED]	5
[REDACTED]	55
[REDACTED]	80

**140**

Consulting rate: \$400 per hour

**Invoice Total            \$56,000**



# Exhibit 6

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON TALCUM  
POWDER PRODUCTS MARKETING, SALES  
PRACTICES AND PRODUCTS LIABILITY  
LITIGATION**

**MDL NO. 16-2738 (FLW) (LHG)**

***THIS DOCUMENT RELATES TO ALL CASES***

**EXPERT REPORT OF CHRISTIAN MERLO, MD, MPH  
FOR GENERAL CAUSATION *DAUBERT* HEARING**

Date: February 25, 2019



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Christian Merlo, M.D., M.P.H.



## **I. SCOPE OF REPORT**

I was asked to address fundamental tenets of epidemiology, to review the epidemiology related to the potential association between perineal talc use and ovarian cancer, to review plaintiffs' epidemiology experts' reports, and to offer my opinions on their methodologies.

All of the opinions in this report are stated to a reasonable degree of scientific certainty.

I am being compensated at a rate of \$530 per hour for record review and drafting my report and \$720 per hour for testimony.

My curriculum vitae, a list of literature that I have reviewed, and a list of testimony I have provided in the last four years may be found in Appendices A, B and C.

## **II. PROFESSIONAL QUALIFICATIONS**

My name is Christian Merlo. I am a licensed physician in the state of Maryland and am board certified in internal medicine, pulmonary medicine and critical care medicine. I am an attending physician at the Johns Hopkins Hospital and the Johns Hopkins Bayview Medical Center and care for patients both in the hospital and in our outpatient centers. I am Associate Professor of Medicine in the Division of Pulmonary and Critical Care Medicine at the Johns Hopkins University School of Medicine, and in addition, I am Associate Professor of Epidemiology in the Department of Epidemiology at the Johns Hopkins Bloomberg School of Public Health. I am also a member of the *Alpha Omega Alpha* honor society for medicine.

I have provided patient care and consultation as a clinical physician and have taught medicine in the fields of general medicine, pulmonary medicine and critical care medicine for more than 18 years.

I received my doctorate in medicine at Georgetown University School of Medicine and completed my residency in internal medicine at Georgetown University Medical Center, where I also served as Chief Resident. I completed a four-year fellowship in Pulmonary and Critical Care Medicine at the Johns Hopkins Hospital, and during this period in time, I also received a master's degree in public health from the Johns Hopkins Bloomberg School of Public Health.

I was offered a faculty position in 2004 as Instructor in Medicine at the Johns Hopkins University School of Medicine, and was promoted to Assistant Professor of Medicine in 2006. In 2009, I was awarded a joint faculty appointment as Assistant Professor of Epidemiology at the Johns Hopkins Bloomberg School of Public Health, and in 2015, I was promoted to Associate Professor of Medicine and Epidemiology.

I am the Associate Program Director of the Adult Cystic Fibrosis Program at the Johns Hopkins Cystic Fibrosis Center, one of the largest cystic fibrosis centers in the country, and in addition, I am the Director of Research for both the Adult Cystic Fibrosis Program and the Lung Transplant Program at the Johns Hopkins Hospital. I am also an Associate Program Director for Research and Scholarship for the Osler Medical Residency

program. I have specific expertise in the clinical care of patients with cystic fibrosis and those who undergo lung transplantation, as well as in the care of patients with other pulmonary diseases or those that require critical care therapies. My research involves the design of clinical studies investigating the impact of environmental and infectious exposures on outcomes for patients with cystic fibrosis and those who undergo lung transplantation.

I am currently principal investigator or co-investigator on many NIH-funded and pharmaceutical industry-sponsored clinical trials. I have authored or co-authored more than 70 manuscripts, book chapters and commentaries on topics involving cystic fibrosis and lung transplantation, as well as on topics in general pulmonary medicine and critical care medicine. As a clinical investigator, I have had rigorous training and have expertise in clinical epidemiology, with specific training in clinical trial design, conduct and analysis. My ties with the School of Public Health have provided ongoing collaboration to help research the epidemiologic nature of the exposure/outcome causal pathway in diseases involving internal medicine, pulmonary medicine and critical care medicine.

I am also an expert in the methodologic approach to the study of disease and have more than 15 years of experience teaching coursework on study design and analysis, as well as conducting research on the epidemiologic nature of the exposure/outcome relationship with a strong command of the strengths and limitations of epidemiologic investigation.

### **III. FUNDAMENTAL PRINCIPLES OF EPIDEMIOLOGY**

Although there are many definitions of epidemiology, a widely accepted definition describes epidemiology as:

*the study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to the control of health problems.*<sup>1</sup>

Epidemiology is a scientific discipline that relies heavily on an unbiased approach to the collection, analysis and interpretation of data. Epidemiology places an emphasis on the frequency and rate of health events as well as how personal characteristics such as demographics, socioeconomic status, behaviors and environmental exposures play a role in health-related events. Epidemiology is a science, and epidemiologic studies, when designed, conducted, analyzed and interpreted appropriately, can be powerful tools in the critical examination of the causal pathway between exposure and outcome.

#### **A. Fundamentals Of Epidemiologic Study Design**

Researchers often have to choose a study design based on the research question, as not all study designs are appropriate for all questions. Many research questions are suitable to be answered using a classic experimental design such as the randomized controlled trial. For instance, it may be appropriate to use a randomized controlled trial design to investigate

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<sup>1</sup> See, e.g., Centers for Disease Control & Prevention, Principles of Epidemiology in Public Health Practice, Third Edition, An Introduction to Applied Epidemiology and Biostatistics, Lesson 1: Introduction to Epidemiology, <https://www.cdc.gov/opphss/csels/dsepd/ss1978/lesson1/section1.html> (footnote omitted).

the effect of a new cholesterol lowering agent on mortality in patients with heart disease. An example of this is the Scandinavian Simvastatin Survival Study,<sup>2</sup> in which researchers studied 4,444 patients with heart disease who were either treated with simvastatin or placebo. The investigators found a significant reduction in the risk of death from heart disease in the simvastatin group compared to placebo.

Other research questions are not suitable for an experimental design in humans because of the potential for harm, lack of equipoise or ethical concerns. One such example is the effect of cigarette smoking on risk of death and risk of death from lung cancer. In order to attempt to answer this, researchers would not be able to use an experimental design, and more likely would have to use an observational study design. Doll and Hill<sup>3</sup> sent out a short but detailed questionnaire asking more than 59,000 British physicians about smoking habits and obtained follow-up information regarding mortality and lung cancer risk. In this very large observation cohort, Doll and Hill were able to demonstrate a significant increase in all-cause mortality as well as deaths due to lung cancer among cigarette smokers when compared to non-smokers.

Sometimes, the experimental study design is appropriate, and other times, an observational study design is necessary, but it is only with careful and detailed attention to the study design (study type, study size, exposure assessment, attempt to limit bias and confounding), conduct and analysis that the cause of disease can possibly be determined.

### ***B. Limitations Of Epidemiologic Study Design***

All epidemiologic studies have the advantage and limitation of studying humans rather than experimental animals. Each epidemiologic study design (detailed in the **STUDY DESIGN CONSIDERATIONS** section), however, not only has its strengths, but also weaknesses.

For example, consider the design of an epidemiologic study to evaluate the question:

*“Does regular aerobic exercise decrease the risk of heart disease?”*

A randomized controlled trial, one might think, would be the most rigorous approach and the method most similar to a laboratory scientist working in a highly controlled environment with experimental animals. Suppose researchers choose a group of subjects who don’t exercise regularly, divide the group randomly into an intervention group, who are instructed to perform aerobic exercise for 30 minutes three times a week, and a control group, who are instructed to continue with a low exercise lifestyle. The investigators will follow both groups looking for signs of heart disease, and if they are correct, subjects who exercise will get less heart disease. With this study design there may be a problem with controlling how much the subjects exercise. In the laboratory, a scientist can control exactly how much an experimental animal exercises, but in the real world this

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<sup>2</sup> The Scandinavian Simvastatin Survival Study Group, *Design and baseline results of the Scandinavian Simvastatin Survival Study of patients with stable angina and/or previous myocardial infarction*. (1993) 71 Am J Cardiol 393.

<sup>3</sup> Doll & Hill, *The mortality of doctors in relation to their smoking habits*. (1954) 328 (7455) BMJ. 1529 .

may be difficult to control. The intervention group may become lazy and not exercise, while the control group might have concern about heart disease and increase exercise, which would affect the study results.

The researchers might attempt a cohort study and follow a large group of people without heart disease over a period of time and ask them detailed questions about exercise and then after several years compare the rate of heart disease among those who exercise regularly to those who do not. Again, if the researchers are correct, patients who exercise regularly will develop less heart disease. One potential problem with this design is that people who exercise regularly may differ in other ways from people who do not exercise regularly. For example, the people who exercise regularly might be more likely to eat healthier and less likely to smoke and have a reduced risk of heart disease that is unrelated to exercise.

The researchers might also choose to perform a case-control study and identify a group of people with heart disease from the hospital coronary care unit as well as a comparable group from the hospital without heart disease. The investigators would then question both groups about their exercise over the past several years and classify each as either exercising regularly or not exercising regularly. Once again, if the researchers are correct, the patients with heart disease will report less exercise than controls. One potential problem with this approach is that people may not be able to remember their exercise patterns, or those with heart disease might feel self-conscious about reporting true exercise patterns and the information obtained about the exposure may not be reliable.

#### **IV. EVALUATING THE ACCURACY OF EPIDEMIOLOGIC STUDIES**

##### ***A. Accuracy Of An Epidemiologic Study***

In an ideal setting, all epidemiologic studies would be designed, conducted, analyzed, and interpreted in a fashion that eliminated sources of error. One of the major goals for epidemiologists is to minimize error as much as possible. Similarly, it is important for those who read and use the epidemiologic literature to be cautious in how the information is interpreted. As such, it is important to understand the factors that can influence the accuracy of epidemiologic study as errors can arise from three main sources – bias, confounding and random error.

Accuracy requires both validity and precision. Bias and confounding affect the validity of a study, while random error affects the precision of a study.

##### ***B. Validity***

Validity of epidemiologic studies is defined as the “degree to which inferences are warranted given the methods and study population chosen.”<sup>4</sup> There are two major types of validity – internal validity and external validity. Internal validity represents how well the study findings, aside from random error, represent the truth in the population being studied. The internal validity of an epidemiologic study can be challenged by systematic error caused by either or both of bias and confounding. This systematic error in the study design, conduct, analysis or interpretation can lead to either artificial elevation or artificial

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<sup>4</sup> Oleckno, *Epidemiology: Concepts & Methods* (2008).

reduction in the measures of association between exposure and outcome. External validity, sometimes referred to as generalizability, is the extent to which the results of the study can be applied to populations other than the population under investigation. It is often felt that internal validity is more important than external validity because if a study is not valid, then why would one generalize a non-internally-valid study to another population. The above-mentioned Scandinavian Simvastatin Survival Study<sup>5</sup> results were believed to be internally valid, and it was also felt to be reasonable to apply these results to other populations.<sup>6</sup>

### **C. Bias**

Bias is a type of systematic non-random error in the design and/or conduct of an epidemiologic study. Bias can have a dramatic effect on the internal validity of a study and because of this, can affect the accuracy of the study. In general, bias can be broken down into two main categories, known as selection bias and information bias. Both of these types of bias can lead to either an overestimation or underestimation of risk in epidemiologic studies. Although bias can be present in all types of studies, bias can be a particularly significant concern in observational studies, especially in those studies that are poorly designed.

Selection bias refers to a systematic error due to the way in which subjects are selected for the study. This type of bias can occur when the subjects in the study population differ from the subjects in the source population. This can occur in a cross-sectional or case-control study when the frequency of the exposure or outcome differs systematically between the study population and the source population. Because of this, selection bias can sometimes lead to an association when one does not actually exist. For instance, an investigator interested in researching whether coffee drinking is associated with a specific type of cancer designs a case-control study and obtains cases from an oncology clinic. The investigator obtains controls from a nearby heartburn clinic. The study is performed, and the investigator finds that coffee drinkers are 1.5 times more likely to develop a specific type of cancer. Since controls are recruited from a different clinic than the cases, it is possible that controls may be systematically different from cases in a way that may affect the study results. In fact, since controls were recruited from a nearby heartburn clinic where patients are routinely instructed to reduce or stop coffee drinking, controls are less likely to be coffee drinkers than all people who would be eligible controls and lead to an overestimate of risk due to selection bias.

Information bias refers to a systematic error due to measurement errors that leads to misclassification of study subjects with regards to either exposure or outcome. Information bias tends to occur during the data collection portion of an epidemiologic study. This misclassification of either exposure or outcome can be characterized as either differential or nondifferential. Differential misclassification can occur when the likelihood of misclassification is different between the study and comparison groups. Differential misclassification may lead to either overestimation or underestimation of the true value of the measure of association. If the cases in a case-control study are more likely to be

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<sup>5</sup> The Scandinavian Simvastatin Survival Study Group. *Design and baseline results of the Scandinavian Simvastatin Survival Study of patients with stable angina and/or previous myocardial infarction.* (1993) 71 Am J Cardiol 393.

<sup>6</sup> *Id.*

misclassified as exposed than the controls, then the study will tend to overestimate the true estimate of risk (odds ratio).

For example, suppose an investigator is interested in studying whether high blood pressure is associated with drinking sugary drinks. A case-control study is designed, and the investigator finds 200 cases with high blood pressure and 200 controls with normal blood pressure. The investigator then asks questions about sugary drink habits during the previous five years. The responses are collected and analyzed (table a), and there is a statistically significant increase in risk of high blood pressure with drinking sugary drinks (OR: 3.67;  $p < 0.001$ ), suggesting sugary drinks are associated with high blood pressure. If cases are systematically more likely to report sugary drink usage than controls (differential misclassification because of the belief that sugary drinks may cause high blood pressure), then this will lead to an overestimation of the true estimate of risk. In reality, if there was no increase (table b) in reporting sugary drink consumption among cases (no misclassification), there would be a non-statistically significant estimate of risk (OR: 1.35;  $p = 0.13$ ).

a.

	Study			
	High BP	No high BP		
Sugary drinks	150	90	OR=3.67	$P < 0.001$
No sugary drinks	50	110		
	200	200		

b.

	Truth			
	High BP	No high BP		
Sugary drinks	105	90	OR=1.35	$P = 0.13$
No sugary drinks	95	110		
	200	200		

Nondifferential misclassification can occur when there is likely an equal proportion of misclassification of exposure status among those with and without an outcome or of outcome status among those with and without an exposure. This type of misclassification typically results in a dilution of the effect of exposure on outcome and is more likely to result in no association when an association between exposure and outcome actually exists.

One specific type of bias that leads to misclassification and that is common in case-control studies is known as recall bias. It often results from the fact that cases tend to remember past exposures more than controls. It may also arise if cases are more likely than controls to investigate whether certain risk factors increase the risk of developing a certain disease. Recall bias is often less likely to occur when both cases and controls are patients, for example, in hospitalized patients,<sup>7</sup> where the degree of thinking about a possible exposure or outcome is likely to be at similar levels. Consider again the above example of the investigator who is trying to determine if there is a relationship between sugary drinks and high blood pressure. If the cases tend to recall and report more sugary drink consumption simply because they have reflected more on their past experiences, recall bias

<sup>7</sup> Schultz & Grimes, *Case-control studies: research in reverse*. (2002) 359(9304) Lancet 431; Schlesselman, *Case-control studies: design, conduct, analysis* (1982).



could result in an overestimation of the measure of risk between the sugary drinks and high blood pressure.

As particularly pertinent here, in one case-control study involving the potential association between perineal talc use and ovarian cancer,<sup>8</sup> the investigators examined whether cases and controls reported talc use more frequently if they were interviewed after 2014, which is the year when two widely publicized lawsuits concerning talc use were filed, as opposed to before that year. For those interviewed prior to 2014, approximately the same percentage of cases and controls reported genital talc use (36.5% for cases, 34.0% for controls). For those interviewed after 2014, cases reported talc use 51.5% of the time, while the percentage of controls reporting talc use remained about the same (34.4%). This is a clear demonstration of the effect of recall bias in case-control studies. Critically, that study found a statistically significant risk of ovarian cancer for those who were interviewed after 2014 at 2.91 (95% CI: 1.70-4.97). For those interviewed prior to 2014, no statistically significant association was found.<sup>9</sup> As discussed in Section VIII.B below, such concerns of recall bias could have affected pre-2014 studies as well.

Selection and information bias can best be controlled and prevented during the design and conduct of a study. This means that investigators must recognize the potential sources of bias and take precautions to minimize this bias. Methods have been developed to prevent or minimize bias in epidemiologic studies. Some of these include attempts to standardize data collection, pilot test data collection instruments, use objective methods to measure exposure and outcome status, verify subject response from other sources and obtain multiple measurements of exposure and outcome status.

#### ***D. Confounding***

In epidemiology, confounding is a misrepresentation of the true effect of an exposure on an outcome due to an association between the exposure and another factor. This factor is often referred to as a confounder, and like bias, confounding is a systematic, non-random error that can affect the internal validity of a study. Confounding can result in an overestimation or underestimation of the true effect of an exposure on an outcome. In general, for another factor to confound the effect of an exposure on the outcome, three conditions must be met: (1) the factor must be associated with the exposure; (2) the factor must be associated with the outcome; and (3) the factor must not represent a step in the causal pathway between exposure and outcome. Many times, epidemiologists do not know what extra factors will confound an actual effect of an exposure on an outcome, but it is important for suspected factors to be considered as potential confounders. Experienced epidemiologists are usually able to anticipate suspected confounders given previous experience in similar studies or based on previous studies looking at a similar exposure outcome relationship.

The Sister Study, which I discuss in more detail below, is one example of potential confounding affecting the measurement of the effect of genital talc exposure.<sup>10</sup> In that

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<sup>8</sup> Schildkraut et al., *Association between Body Powder Use and Ovarian Cancer: The African American Cancer Epidemiology Study (AACES)*. (2016) 25(10) Cancer Epidemiol Biomarkers Prev. 1411.

<sup>9</sup> *Id.*

<sup>10</sup> Gonzalez et al., *Douching, Talc Use, and Risk of Ovarian Cancer*. (2016) 27 Epidemiology 797.

study, in addition to talc use, participants were also asked about their douching habits. Of the 50,884 women who completed questionnaires, 154 women developed ovarian cancer. Ever douching during the 12 months prior to the study was associated with a statistically significant risk of ovarian cancer (HR: 1.8; 95% CI: 1.2-2.8) when compared with never douching after adjusting for confounders.<sup>11</sup> In contrast, there was no statistically significant increase risk of ovarian cancer (HR: 0.73; 95% CI: 0.44-1.2) with ever talc use during the 12 months prior to the study when compared with never talc use after adjusting for confounders.<sup>12</sup> There was no change in the estimated effect of talc use after adjustment for douching, and similarly, there was no change in the estimated effect of douching after adjusting for talc use. If those who use talc are more likely to douche, as is demonstrated in this and other studies,<sup>13</sup> and douching has a significant effect on the risk of ovarian cancer in this study, prior studies that have revealed a significant effect of talc on ovarian cancer may have been confounded by douching.

Although the amount of confounding is the degree to which the measure of association is affected, it is not appropriate to evaluate confounding using statistical tests of significance. In order to ensure the validity of an epidemiologic study, all attempts should be made to control confounding. While bias usually occurs in the study design and data collection phases of an epidemiologic study, confounding usually occurs during the design and analysis phases. Epidemiologists can work to control confounding in the design phase by restricting subjects to only certain characteristics, matching to attempt to create study and comparison groups that are similar with respect to potential confounders, and randomization to decrease confounding by increasing the likelihood that the study group is similar to the comparison group with regard to known factors, as well as unknown potential confounders.

#### ***E. Precision***

Precision is a measure of the amount of nonsystematic or random error that is present in the study. Random error is variability in a measure that is simply due to chance, and it represents unexplained error in a study. In epidemiologic studies, a precise result would be very easily replicated. Random errors tend to cause inconsistency between different studies and may make it less likely that investigators will find an association between exposure and outcome.

#### ***F. Random Error***

Random error affects the precision (and thus, the accuracy) of an epidemiologic study. Measurement error and sampling variation are the two main components of random error. Measurement error occurs because of an error in the measuring of the value of a variable. This may be the result of inaccurate measuring devices or due to the subjective type of some exposures or outcomes. Measurement error can be minimized by taking multiple measurements for a certain exposure or outcome. For instance, assume the above case-control study designed to investigate the effect of sugary drinks on blood pressure.

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<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> Rosenblatt et al., *Characteristics of women who use perineal powders*. (1998) 92(5) *Obstet Gynecol* 753.

Investigators might consider taking several measures of blood pressure and using the average to minimize measurement error. A second form of random error, sampling variation, can occur because samples used in an epidemiologic study are only estimates of the desired population of interest to study. Consider again the above case-control study in which investigators report the odds ratio of 1.35 as the risk estimate of the effect of sugary drinks on high blood pressure. Suppose the investigators replicated the study using a new sample of the same size and found that the odds ratio was now 1.8. Assuming systematic errors were controlled for in study design, data collection and analysis, this difference can be explained by random error/sampling variation. A third sample might reveal an odds ratio of 1.1 or 2.5, which demonstrates that sampling variation is both unpredictable and not reproducible. In general, epidemiologists try to reduce sampling variation by increasing sample size. The stronger the relationship between the exposure and outcome, the smaller the group of patients that need to be studied for this relationship to be apparent. If the group being studied is too small, then the causal relationship may be missed, or spurious results may show up by sampling variation and random error.

## **V. STUDY DESIGN CONSIDERATIONS**

The purpose of epidemiology is to establish associations between exposures and outcomes that may uncover clues to causation. Epidemiologists can explore the relationship between exposure and outcome in humans in real-world situations by observing (observational study designs) or intervening to a limited extent (experimental study designs), as opposed to controlling all aspects of an experiment in the laboratory. Epidemiologists may also gather data from many studies, either observational or experimental (meta-analysis study designs) and summarize the information in an attempt to demonstrate associations between exposure and outcome. As such, there are many different study designs in epidemiologic research in humans, each with strengths and weaknesses.

### ***A. Case Reports And Case Series***

Individual level observations can be documented in a case report, a particular clinical situation involving one unique patient, or in a case series, a description of a group of patients with similar clinical findings or conditions. Case reports and case series are helpful tools in generating hypotheses about associations between exposures and outcomes. However, the lack of a comparison group and the likely presence of bias and confounding limit validity, and therefore limit the ability of these types of epidemiologic descriptions to establish causal associations between exposure and outcome.

### ***B. Cross-Sectional Studies***

A common epidemiologic study design used in the initial attempts to evaluate associations between exposures and outcomes is the cross-sectional study. In this type of study, both the exposure and outcome are evaluated simultaneously in each study participant. This approach is sometimes referred to as a prevalence study, as cases of disease or outcome identified are prevalent cases of the outcome being investigated. It is impossible to determine the temporality between exposure and outcome with this epidemiologic study design because of the temporal bias that may exist if the disease causes the exposure. For instance, prevalent cases of asthma may be less likely to own a cat than those without asthma. As patients with asthma may have been instructed to not own a cat,

this relationship might lead investigators to conclude that cat ownership is protective against asthma, leading to a phenomenon known as reverse causality. In addition to temporal bias, selection bias due to survivorship may also be present in cross-sectional studies. This may result if exposure in cases leads to shortened survival than those cases who are unexposed. Similar to case-reports and case-series, cross-sectional studies are often used to generate hypotheses about potential causal associations between exposure and outcome.

### ***C. Case-Control Studies***

Another common study design used to evaluate the effect of an exposure on an outcome is known as a case-control study. In this type of epidemiologic study, cases are defined as those with a particular outcome and non-cases or controls are defined as those without a certain outcome. Exposure is then retrospectively evaluated and compared between the cases and controls. Thus, in a case-control study, the prevalence of the exposure of interest should be higher among those with the outcome (cases) than those without the outcome (controls). In general, case-control studies provide more information on the temporal relationship between exposure and outcome than cross-sectional studies. However, case-control studies remain susceptible to other forms of bias. Selection bias can occur in a case-control study when the relationship between exposure and outcome differs systematically between the study population and the source population. Because of this, selection bias can sometimes lead to an association when one does not actually exist. Recall bias is common in case-control studies and results from the cases or subjects with disease having a tendency to remember past exposures more than controls. As mentioned above, it may also arise if cases are more likely to investigate possible factors that may increase the risk of developing a certain disease. Recall bias is often less likely to occur when both cases and controls are patients, for example, in hospitalized patients<sup>14</sup> as compared to population-based case-control studies where the degree of thinking about a possible exposure or outcome is likely to be at similar levels.

### ***D. Cohort Studies***

A cohort design assigns an individual as either exposed or unexposed and then that individual is followed over time to see if a particular outcome of interest develops. In general, there are two main types of cohort studies – prospective and retrospective. A prospective cohort design establishes exposure status in the beginning of a study and potentially repeatedly during the study, and then the outcome status for each individual is determined during a follow-up period that extends into the future. In a retrospective cohort design, the exposure and outcome have already occurred (as in the use of administrative or registry data), and the exposure status of each individual is determined from a time period that existed in the past with the outcome then being determined during a time period after exposure that may extend to the present. Temporality is established whether a cohort study is prospective or retrospective in design because the exposure status is always determined prior to evaluating outcome status. In general, cohort studies provide more evidence for a causal relationship between exposure and outcome, and can often study many exposure-outcome relationships with less chance for bias and confounding than case-control studies if

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<sup>14</sup> Oleckno (2008) at 207; Infante-Rivard, *Hospital or Population Controls for Case-Control Studies of Sever Childhood Diseases?* (2003) 157(2) Am J Epidemiol 176.

the design, conduct, data collection and analysis are properly performed. However, cohort study designs also remain susceptible to certain types of bias and confounding, are often very expensive, take a long time to conduct and may be difficult to perform, especially if the outcome of interest is rare.

### ***E. Experimental Studies***

Unlike an observational study, where exposure is not under the control of the investigator, an experimental study is one in which the exposure (intervention) is controlled directly by the investigator. One such experimental study design – the randomized-controlled clinical trial – is a planned epidemiologic experiment where subjects are randomly assigned to an exposure (intervention) or control group to evaluate the effect of the exposure on outcome. Randomized controlled clinical trials are considered the gold standard of epidemiologic studies. Although there are many advantages to an experimental study design, experimental studies are still subject to the effects of bias and confounding if not designed and conducted properly, and there are instances when this design is not suitable to evaluate the causal association between exposure and outcome because of potential for harm, lack of equipoise or ethical concerns.

### ***F. Meta-Analysis***

Epidemiologists may use multiple studies that address the same research question to provide an overall statistical summary of the results. This process is known as meta-analysis and is useful when individual studies tend to be inconclusive because of small sample size. A meta-analysis can provide a precise estimate of the effect of an exposure on an outcome of interest by combining the results of relevant studies by using a systematic approach and analysis. Meta-analyses can also help to provide consensus about the effectiveness of interventions, as well as insight or explanation for differences in individual trial results. Meta-analysis is a type of systematic review that utilizes a comprehensive, rigorous and standardized approach to selecting, assessing and synthesizing all relevant studies on a given topic. Systematic reviews that summarize studies without combining the results statistically are often called qualitative systematic reviews, while those that also combine study results statistically to produce an overall summary effect are referred to as quantitative systematic reviews, and are synonymous with meta-analyses. There are fundamental steps that must be followed to ensure the quality of a meta-analysis. These include (a) defining the research question, (b) defining the criteria for study selection, (c) structuring a review of the literature for all eligible studies, (d) structuring data abstraction, (e) reviewing the methods and results of each study critically, (f) summarizing the results of each study using a standard format, (g) using proper statistical tests to provide a summary effect, (h) assessing variation (heterogeneity) between studies and (i) reviewing, interpreting and reporting the findings.<sup>15</sup>

The idea of a meta-analysis is to combine the results of individual studies so that a summary point estimate can be reached that describes the strength of association between exposure and outcome. There are different approaches to modelling data between studies, and it is important to understand that these approaches may produce different results. Fixed-effects models assume that the effect of exposure on outcome is equal in all studies

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<sup>15</sup> Oleckno (2008).



included in the meta-analysis, while random-effects models assume that the effect of exposure on outcome varies between each included study due to both actual differences in effect and random error. In general, when the findings of the included studies are similar, both models yield similar summary estimates, but when the findings of the included studies vary appreciably, the models may produce conflicting results. A statistical test of heterogeneity is oftentimes performed to evaluate whether differing results from the included studies are due to chance alone. If unlikely due to chance, then a random effects model may be more appropriate.

It is also important to understand that in addition to the great deal of preparation and structured organization that is involved in conducting a meta-analysis, it is of utmost importance to vigilantly examine the accuracy of the included individual studies when relying on meta-analyses. Many of plaintiffs' epidemiologists, for instance, premise their causation opinions in large part on the various meta-analyses assessing the effect of exposure to talc on ovarian cancer.<sup>16</sup> But, when it comes to concerns over bias and confounding, a pooled analysis or a meta-analysis will only be as good as the included studies. And while some of plaintiffs' experts have performed their own meta-analyses, the underlying limitations of the included studies are not lessened or removed simply by performing additional meta-analyses using the same studies with different groupings.

## **VI. EPIDEMIOLOGIC STUDIES OF TALC POWDER AND OVARIAN CANCER**

In order to understand the relationship between talc exposure and ovarian cancer, I have performed a search of the peer-reviewed literature. I identified 44 individual studies investigating the exposure/outcome relationship between talcum powder use and ovarian cancer. The individual studies were evaluated with attention to study design, accuracy, exposure assessment, analysis and validity, while noting both strengths and weaknesses.

### ***A. Summary Of Article Study Designs***

Due to the exposure (talc powder) and outcome (ovarian cancer) being studied, there were no experimental studies, as this study design would not be suitable to evaluate this relationship. The studies identified can be separated into three categories: (1) case-control studies, (2) cohort studies, and (3) meta-analyses. I reviewed 33 case-control studies (two of which pooled data from different studies), four cohort studies, and seven meta-analyses published between 1982 and 2018.<sup>17</sup>

The 33 case-control studies ranged in size from 123 to 4,092 participants. There were seven hospital-based case-control studies and 26 population-based case-control studies that I reviewed. The assessment of exposure varied extensively in the case-control studies and was obtained from responses to questionnaires on the use of talc, diaphragm with talc, diaphragm storage only, all over body talc, genital talc, legs only talc, not genital talc, talcum powder in the perineum, talcum powder on sanitary pads, talcum powder on

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<sup>16</sup> Clarke-Pearson Rep. 7; McTiernan Report 8, 63; Moorman Rep. 10.

<sup>17</sup> I also briefly reviewed the unpublished Taher meta-analysis cited by several of plaintiffs' experts, and it does not affect my analysis. The association it reports is not materially higher than prior studies, and it agrees with IARC's assessment that a causal relationship is merely "possible" in light of current evidence.



diaphragms, after bathing only, baby powder only, deodorizing powder, dusting powder to the perineum, any dusting powder, talc around the abdomen/ perineum, perineal dusting, genital powder application, genital/rectal talc, powder to genitals, powder to diaphragm, or powder to sanitary napkins. All studies included pathologically confirmed cases or cancer registry cases of ovarian cancer. Analyses varied widely among the case-control studies from no adjustment for potential confounders to adjusting for varying degrees of confounding, including age at first birth, age at last birth, age at menarche, age at menopause, tumor behavior, breast feeding, community-based case-control study, diaphragm use, duration of use, exercise, education, frequency of use, family history of breast and ovarian cancer, histologic type, hospital-based case-control study, hair dye use, hormone replacement therapy, hysterectomy, income, use of medications, menopausal status, sanitary napkin use, number of pregnancies, oral contraceptive use, parity, socioeconomic status, timing of use and tubal ligation.

The four cohort studies I reviewed utilized data from the US Nurses' Health Study (NHS), US Nurses' Health Study II, the Women's Health Initiative Observational Study, and the Sister Study and ranged in size from 41,654 to 108,870 participants. The assessment of exposure was obtained from responses to questionnaires on talc use, talc on the perineum or napkin, powder on the genitals, powder on diaphragm, powder on napkin or talc use in the past 12 months. Analyses varied across the different cohort studies with varying degrees of adjustment for potential confounding, including age, age at last birth, menopause status, age at menopause, race, parity, BMI, activity level, breast feeding, oral contraceptive use, duration of oral contraceptive use, estrogen use, postmenopausal hormone use, duration of hormone replacement therapy, tubal ligation, smoking status and family history of breast or ovarian cancer.

### ***B. Case-Control Studies: Hospital-Based***

I identified seven hospital-based case-control studies that have evaluated the potential causative association between talc and ovarian cancer, yielding similar non-statistically significant estimates of risk of ovarian cancer and talc usage.

In 1983, Hartge et al.<sup>18</sup> conducted a hospital-based case-control study of pathologically identified ovarian cancer and frequency matched controls of women in the same hospitals in Washington, DC. Interviews were performed and exposures were categorized as "any" use of talc and "genital" exposure to talc. Among women exposed to "any" talc, the odds ratio of ovarian cancer was not statistically significant at 0.7 (95% CI: 0.4-1.1). Among those who reported talc use on genitals, sanitary napkin or underwear, the odds ratio was not statistically significant at 2.5 (95% CI: 0.7-10.0). The study is limited by small sample size and lack of adjustment for potential confounders.

In 1988, Whittemore et al.<sup>19</sup> similarly completed a hospital-based case-control study of histologically confirmed ovarian cancer cases in pre-menopausal and postmenopausal women between the ages of 18 and 74 with primary epithelial ovarian cancer in Santa Clara County hospitals or at the University of California, San Francisco Medical Center and

<sup>18</sup> Hartge et al., *Talc and Ovarian Cancer*, (1983) 250 J. Am. Med. Ass'n 1844.

<sup>19</sup> Whittemore et. al., *Personal And Environmental Characteristics Related To Epithelial Ovarian Cancer*, (1988) 128 Am J. Epidemiol 1228.

hospitalized controls. In-person interviews were performed, and to evaluate exposure, subjects were asked about whether they had used talcum powder products on the perineum, sanitary pads and/or diaphragms. Participants who responded were asked about frequency and duration of use. Among women who reported perineum only talc use, the odds ratio was not statistically significant at 1.45 (95% CI: 0.81-2.60) after adjustment for parity and oral contraceptive use. There was no trend in increasing duration of treatment, and the risk of ovarian cancer was not statistically significant with increasing frequency of use.

Booth et al.<sup>20</sup> in 1989 performed a hospital-based case-control study of pathologically identified ovarian cancer in women under 65 years of age from 13 hospitals in London and two in Oxford and hospitalized controls. Subjects were interviewed and exposure was obtained through a questionnaire and frequency of talc use was reported as never, rarely, monthly, weekly or daily talc use. There was no statistically significant increase in risk of ovarian cancer between never and daily reported talc use (OR: 1.3; 95% CI: 0.8-1.9) after adjusting for age and social class. There was no trend of increased risk of ovarian cancer with increased frequency of reported talc use, as those participants who reported weekly use had a higher risk estimate (OR: 2.0; 95% CI: 1.3-3.4) than those who reported daily talc use, and no dose-response relationship with frequency of reported talc use was found among those exposed compared to those unexposed after adjusting for age and social class.

Rosenblatt et al.<sup>21</sup> in 1992 reported a hospital-based case-control study evaluating “fiber exposure” generally (with “fiber” defined as asbestos, talc or fiberglass), including “genital fiber use” specifically, which included an assessment of “method of application” in pathologically confirmed cases of ovarian cancer and hospitalized controls between 1981 and 1985 at the Johns Hopkins Hospital. A questionnaire was administered to participants, both by telephone and in the hospital, which was used to obtain reported exposure to talc and presence and length of applying talcum powder to the genital area. There was no statistically significant increase in risk of ovarian cancer with “genital fiber use” (OR: 1.0; 95% CI: 0.2-4.0) after adjustment for parity, or for exposures from diaphragm use with powder (OR: 3.0; 95% CI: 0.8-10.8) after adjustment for parity and education, or genital bath talc exposure (OR: 1.7; 95% CI: 0.7-3.9) in unadjusted analysis. There was also no statistically significant increase in the risk of ovarian cancer with length of exposure (≥ 37.4 years vs. <37.4 years) to “genital fiber use” (OR: 2.4; 95% CI: 1.0-5.8) after adjustment for religion.

Tzonou et al.<sup>22</sup> in 1993 conducted a case-control study among hospitalized patients from two hospitals in Athens, Greece with histologically confirmed ovarian cancer and hospital visitor controls. In-hospital questionnaires were administered and exposure was obtained as reported use of talc in the perineal region. Even though the prevalence of talc usage was low, there was no statistically significant association between reported exposure of talc to the perineum and risk of ovarian cancer (OR: 1.05; 95% CI: 0.28-3.98). The

<sup>20</sup> Booth et al., Risk factors for ovarian cancer: a case-control study. (1989) 60(4) *Br J Cancer*. 592.

<sup>21</sup> Rosenblatt et al., *Mineral Fiber Exposure and the Development of Ovarian Cancer*, (1992) 45 *Gynecologic Oncology* 20.

<sup>22</sup> Tzonou et al., *Hair dyes, analgesics, tranquilizers and perineal talc application as risk factors for ovarian cancer*. (1993) 55(3) *Int J Cancer*. 408.

authors adjusted for age, years of schooling, weight before onset of the disease, age at menarche, menopausal status, age at menopause, parity, age at first birth, tobacco smoking, consumption of alcoholic beverages, consumption of coffee, hair dyeing and analgesics-tranquilizers/hypnotics.

Hartge and Stewart<sup>23</sup> in 1994 reported a case-control study of women diagnosed with pathologically confirmed ovarian cancer in the Washington, DC area between 1978 and 1981. This study analyzed occupational history in women who were diagnosed with ovarian cancer and hospital-based controls. Trained interviewers used a standardized questionnaire that included lifetime job history and exposure to talc on the job. An industrial hygienist conducted an industrial hygiene exposure assessment evaluating each job/industry combination for potential exposure to talc, as well as other potential exposures. The risk of ovarian cancer was not significantly increased for any exposure to talc, regardless of the duration of exposure: <5 years (OR: 0.5; 95% CI: 0.1-1.4), 5-9 years (OR: 0.3; 95% CI: 0.1-1.4), 10+ years (OR: 0.5; 95% CI: 0.2-1.5).

Wong et al.<sup>24</sup> in 1999 reported the results of a hospital-based case-control study in patients with ovarian cancer as determined by the Roswell Park Tumor Registry and hospital-based controls. Exposure was evaluated using a self-administered questionnaire regarding medical history and personal hygiene. There was no statistically significant increased risk of ovarian cancer among participants who ever used talc (OR: 1.13; 95% CI: 0.88-1.44)<sup>25</sup> or among those who used talc on both a sanitary napkin and on the genital or thigh area (OR: 1.1; 95% CI: 0.7-1.7). There was a haphazard non-statistically-significant relationship with duration of talc use over time and risk of ovarian cancer: 1-9 years (OR: 0.9; 95% CI: 0.6-1.5), 10-19 years (OR: 1.4; 95% CI: 0.9-2.2), and 20 years (OR: 0.9; 95% CI: 0.6-1.2) after adjustment for parity, oral contraceptive use, smoking history, family history of epithelial ovarian cancer, age at menarche, menopausal status, income, education, geographic location and history of tubal ligation or hysterectomy.

### ***C. Case-Control Studies: Population-Based***

I identified 26 population-based case-control studies (two from pooled data) that assessed the potential causative association between talc and ovarian cancer, yielding conflicting results.

Cramer et al.<sup>26</sup> in 1982 reported the first epidemiologic case-control study of genital talc use and risk of ovarian cancer. Cases were women diagnosed with ovarian cancer in the Greater Boston area between 1978 and 1981 and identified through pathology logs or tumor boards and confirmed pathologically. Controls were identified through annual

<sup>23</sup> Hartge & Stewart., *Occupation and ovarian cancer: a case-control study in the Washington, DC, metropolitan area, 1978-1981*. (1994) 36(8) J Occup Med. 924.

<sup>24</sup> Wong et al. *Perineal talc exposure and subsequent epithelial ovarian cancer: a case-control study*. (1999) 93 Obstet Gynecol 372.

<sup>25</sup> The Wong paper does not report an odds ratio for ever versus never talc use, but the text of the article contains the information necessary to calculate it. Specifically, the text reports that 221 cases out of 421 total had ever used talc and 311 controls out of 693 total had ever used talc. The calculated odds ratio is 1.13 with a 95% CI of 0.88-1.44 (STATA SE 15.1, StataCorp, College Station, TX).

<sup>26</sup> Cramer et al., *Ovarian cancer and talc: a case-control study*. (1982) 50(2) Cancer 372.

listings of Massachusetts residents and were matched by residence, race and age. Subjects were interviewed in person to evaluate potential exposure to talc through contraceptives, hygiene or surgery. After adjustment for parity and menopausal status, a statistically significant association was found between “any perineal exposure” of talc and risk of ovarian cancer (OR: 1.92; 95% CI: 1.27-2.89).

Harlow and Weiss<sup>27</sup> in 1989 conducted a study of perineal use of powder and the risk of borderline ovarian cancer. Caucasian women aged 20-79 from three counties in Washington State diagnosed as having serous or mucinous borderline ovarian tumor were identified using the Seattle-Puget Sound Cancer Surveillance System during the years 1980 to 1985. Independent pathologic review was performed on 73% of cases. A control group was identified through random digit dialing. Reproductive, sexual and medical history, as well as information on talc exposure, was obtained during an in-person interview. There was no statistically significant increase in risk of borderline ovarian tumors with any perineal exposure to powder (OR: 1.1; 95% CI: 0.7-2.1), baby powder use (OR: 0.8; 95% CI: 0.4-1.9), or unspecified talc use (OR: 1.0; 95% CI: 0.4-2.4) after adjusting for age, parity and use of oral contraceptives. Use of deodorizing powder alone (OR: 3.5; 95% CI: 1.2-28.7) and use of deodorant powder alone or in combined use with another powder (OR: 2.8; 95% CI: 1.1-11.7) were both associated with a statistically significant increase in risk of borderline ovarian tumors after adjusting for age, parity and use of oral contraceptives.

Harlow et al.<sup>28</sup> in 1992 reported a case-control study among women 18 to 76 years of age diagnosed with borderline or malignant epithelial ovarian cancer confirmed pathologically from 10 hospitals in the Boston metropolitan area. Controls were selected from the Massachusetts Town Books. An in-person interview was performed to obtain demographic, occupational and medical history, as well as hygienic practices. Exposure was reported as any genital talc, type of application (sanitary napkin, underwear, partner or application to diaphragm, or dusting powder to the perineum) and brand of application (brand or generic baby powder or deodorizing or other scented powders). Application via dusting to the perineum was associated with a statistically significant risk of ovarian cancer (OR: 1.7; 95% CI: 1.1-2.7) after adjusting for parity, education, marital status, religion, use of sanitary napkins, douching, age and weight. Use of any genital talc was not associated with a statically significant increase in risk of ovarian cancer (OR: 1.5; 95% CI: 1.0-2.1) after adjusting for the same potential confounders. Although there was no statistically significant increase in risk of ovarian cancer with increasing lifetime total applications of talc-containing powders after adjusting for the same potential confounders, there was a statistically significant increase in the risk of ovarian cancer with more than 10,000 total lifetime perineal applications of talc-containing powders in participants with hysterectomy, tubal ligation and use during nonovulatory months (OR: 2.8; 95% CI: 1.4-5.4).

Chen et al.<sup>29</sup> in 1992 conducted a case-control study in China in women with pathologically confirmed cases of epithelial ovarian cancer. Controls were identified from

<sup>27</sup> Harlow & Weiss, *A case-control study of borderline ovarian tumors: the influence of perineal exposure to talc*. (1989) 130(2) Am J Epidemiol. 390.

<sup>28</sup> Harlow et al., *Perineal exposure to talc and ovarian cancer risk*. (1992) 80(1) Obstet Gynecol. 19.

<sup>29</sup> Chen et al., *Risk factors for epithelial ovarian cancer in Beijing, China*. (1992) 21(1) Int J Epidemiol. 23.

the community using a random selection from a neighborhood committee or village. A questionnaire was developed and administered through face-to-face interviews by trained interviewers. There was no statistically significant association with using dusting powder to the lower abdomen and perineum and risk of ovarian cancer (OR: 3.9; 95% CI: 0.9-10.6) after adjusting for education and parity.

Cramer and Xu<sup>30</sup> in 1995 reported on a case-control study of women in the Greater Boston area diagnosed with ovarian cancer. The study combined women diagnosed with ovarian cancer from area hospitals between 1984 and 1987 and confirmed pathologically with a previous study of women diagnosed between 1978 and 1981. Controls were selected from the general population and matched by age and residence. In an unadjusted analysis, talc use was associated with an increase in risk of ovarian cancer (OR: 1.6; 95% CI: 1.2-2.1).

In 1995, Purdie et al.<sup>31</sup> conducted a case-control study in three Australian states of women diagnosed with ovarian cancer that was confirmed pathologically. Controls were drawn at random from the electoral roll and stratified by age and geographic region. Trained interviewers administered a questionnaire in a face-to-face interview, which included questions about marital status, education, ethnicity, height, weight, smoking history, occupation, medical history and history of talc use. Talc use around the abdomen/perineum was associated with an increased risk of ovarian cancer (OR 1.27; 95% CI: 1.04-1.54) after adjusting for parity.

Green et al.<sup>32</sup> in 1997 performed a case-control study using the study population from the Purdie study. Methods for case and control identification were similar to the Purdie study. Ever douching was associated with a non-significant 60% increase in risk of ovarian cancer. Use of talc in the perineal region was associated with an increased risk of ovarian cancer (OR: 1.3; 95% CI: 1.1-1.6) after adjustment for parity, oral contraceptive use, age, education, body mass index, smoking and family history of ovarian cancer. Even though there was a reported 60% increase in risk of ovarian cancer for those who ever-douched, there were no adjustments in multivariable analyses for douching as a potential confounder.

Shushan et al.<sup>33</sup> in 1996 conducted a case-control study of women aged 36 to 64 years with histologically diagnosed primary invasive or borderline epithelial ovarian cancer. Cases were identified through the Israel Cancer Registry. Controls were identified by telephoning randomly selected numbers within the same area codes as the cases. Cases and controls were interviewed using a questionnaire containing details on medical history and exposures. Exposure to talc was recorded as never-seldom and moderate-a lot talc use. A

<sup>30</sup> Cramer & Xu, *Epidemiologic evidence for uterine growth factors in the pathogenesis of ovarian cancer*. (1995) 5 Ann Epidemiol. 310.

<sup>31</sup> Purdie et al., *Reproductive and other factors and risk of epithelial ovarian cancer: an Australian case-control study*. Survey of Women's Health Study Group. (1995) 62(6) Int J Cancer. 678.

<sup>32</sup> Green et al., *Tubal sterilisation, hysterectomy and decreased risk of ovarian cancer*. Survey of Women's Health Study Group. (1997) 71(6) Int J Cancer. 948.

<sup>33</sup> Shushan et al., *Human menopausal gonadotropin and the risk of epithelial ovarian cancer\**. (1996) 65(1) Fertil Steril. 13.



larger proportion of cases reported moderate-a lot of talc use when compared with controls (10.5% vs. 5.6%;  $p=0.04$ ) without adjusting for potential confounders.

Chang and Risch<sup>34</sup> in 1997 reported a case-control study among women diagnosed with histologically confirmed borderline and invasive ovarian cancers in Toronto and southern Ontario. Controls were identified through the Ontario Ministry of Finance and random selection based on geographic residence. A questionnaire was developed and administered in-person, in-home. Exposure to talc was evaluated by reported regular talc use, use of talc/cornstarch combination, talc use with a sanitary napkin, talc use after bathing as well as after bath uses per month, and years of after bath use. Although there was a significant increase in risk of ovarian cancer with any talc exposure (OR: 1.42; 95% CI: 1.08-1.86), there was no dose-response, and in fact there was a non-statistically significant inverse trend for after bath uses per month: <10 (OR: 1.84; 95% CI: 1.24-2.73), 10-25 (OR: 1.13; 95% CI: 0.74-1.72), >25 (OR: 0.95; 95% CI: 0.61-1.49) and for years of after bath use: <30 (OR: 1.7; 95% CI: 1.09-2.64), 30-40 (OR: 1.44; 95% CI: 0.96-2.15), >40 (OR: 0.87; 95% CI: 0.54-1.38) after adjusting for age at time of interview, years of oral contraceptive use, number of full-term pregnancies, average duration of breastfeeding per pregnancy, the occurrence of a tubal ligation or hysterectomy, and having a mother/sister with ovarian or breast carcinoma.

Cook et al.<sup>35</sup> in 1997 conducted a case-control study of women diagnosed with invasive or borderline epithelial ovarian cancer from records of the Cancer Surveillance System of western Washington State from 1986 through 1988. Controls were identified by random digit dialing of a larger control pool for other studies of cancer in women. Information regarding genital powder exposure was collected by in-person interviews. The occurrence of lifetime genital powder application and the exclusive use of types of genital powder application, including perineal dusting, diaphragm storage in powder, powder on sanitary napkins and genital deodorant spray, were collected. Reported exposure also included cumulative lifetime days of use for perineal dusting, cumulative lifetime months for diaphragm storage in powder, cumulative lifetime months for powder on sanitary napkins and cumulative lifetime months for genital deodorant spray. The use of different types of powder, including talcum powder, baby powder, cornstarch, deodorizing powder, bath or body powder and unspecified powder, was also reported. Although there was an increase in risk of ovarian cancer in women who dusted their perineal areas with powder after bathing (OR: 1.8; 95% CI: 1.2-2.9), there was no statically significant increase in risk of ovarian cancer with increasing cumulative lifetime days of any perineal dusting. There was also no statistically significant increase in risk of ovarian cancer with exclusive use of talcum powder (OR: 1.2; 95% CI: 0.6-2.5) or with the use of any talcum powder (OR: 1.6; 95% CI: 0.9-2.8) after adjusting for age.

Godard et al.<sup>36</sup> in 1998 reported a case-control study of women with histologic diagnosis of ovarian cancer through the gynecologic oncology clinics of two large teaching

<sup>34</sup> Chang & Risch, *Perineal talc exposure and risk of ovarian carcinoma*. (1997) 79(12) Cancer. 2396.

<sup>35</sup> Cook et al., *Perineal powder exposure and the risk of ovarian cancer*. (1997) 145(5) Am J Epidemiol. 459.

<sup>36</sup> Godard et al., *Risk factors for familial and sporadic ovarian cancer among French Canadians: a case-control study*. (1998) 179(2) Am J Obstet Gynecol. 403.



hospitals in Montreal in 1995 and 1996. Controls were obtained through random digit dialing. A questionnaire was developed and administered either in-person or on the phone to obtain medical history and reported exposure to talc on perineum. Talc on the perineum was not statistically associated with an increase in ovarian cancer (OR: 2.49; 95% CI: 0.94-6.58) after adjusting for age at diagnosis, age at last childbirth, age at menarche, age at last oral contraceptive use, tubal ligation or hysterectomy and alcohol use.

Cramer et al.<sup>37</sup> in 1999 conducted a case-control study of women with newly diagnosed ovarian cancer in eastern Massachusetts or New Hampshire identified through tumor boards and statewide cancer registries with review of pathology reports. Controls were identified through random digit dialing. Participants were interviewed in-person using a standardized questionnaire and asked if they regularly used talc, baby powder, or deodorant powder dusted or sprayed on “feet, arms, or other non-genital areas, to the genital or rectal area, on sanitary napkins, or on underwear” as well as a husband’s use of powder in his genital area. “[T]ypes of powder(s) used, applications per month and total years of use were assessed in talc users.” Any reported personal genital exposure was associated with increased risk of ovarian cancer (1.60; 95% CI: 1.18-2.15) after adjusting for age, study center, tubal ligation, BMI, parity, oral contraceptive use, or primary relative with breast or ovarian cancer. Risk of ovarian cancer increased and then fell (inverse relationship) with increasing years of talc use and with increasing total applications, although these estimates were not statistically significant.

Ness et al.<sup>38</sup> in 2000 reported a case-control study of women diagnosed with ovarian cancer who were identified from 39 hospitals in the Delaware Valley region. Controls were identified through random digit dialing. Statistically significant associations were observed for the use of talc on the feet, etc. (OR: 1.4; 95% CI: 1.1-1.6), the genital/rectal area (OR: 1.5; 95% CI: 1.1-2.0), sanitary napkins (OR: 1.6; 95% CI: 1.1-2.3) and underwear (OR: 1.7; 95% CI: 1.2-2.4) after adjusting for age, number of pregnancies, family history of ovarian cancer, race, oral contraceptive use, tubal ligation, hysterectomy and breast-feeding. Risk of ovarian cancer increased and then fell (inverse relationship) with increasing years of talc use and with increasing total applications, although these estimates were not statistically significant.

Mills et al.<sup>39</sup> in 2004 reported a case-control study of epithelial ovarian cancer in 22 counties of Central California and identified cases through two regional cancer registries as women diagnosed with pathologically confirmed epithelial ovarian cancer from 2000 through 2001. Controls were women 18 years or older selected by random digit dialing. All cases and controls were interviewed by telephone to obtain information on history of adult use of talcum powder in the genital area, calendar year(s) of use, frequency of use, and total duration of use. Although there was a statistically significant increase in risk of ovarian cancer with ever talc use (OR: 1.37; 95% CI: 1.02-1.85) after adjusting for age, race/ethnicity, duration of oral contraceptive use and breast feeding, there was no clear

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<sup>37</sup> Cramer et al., *Genital talc exposure and risk of ovarian cancer*. (1999) 81(3) Int J Cancer. 351.

<sup>38</sup> Ness et al., *Factors related to inflammation of the ovarian epithelium and risk of ovarian cancer*. (2000) 11(2) Epidemiology 111.

<sup>39</sup> Mills et al., *Perineal Talc Exposure and Epithelial Ovarian Cancer Risk in the Central Valley of California*. (2004) 112 Int’l J. Cancer 458.

dose-response with relation to frequency and duration of talc use and risk of ovarian cancer after adjusting for the same potential confounders. There was a haphazard relationship between reported frequency of use and risk of ovarian cancer, with estimates increasing with rare to several time a month use, then decreasing with 1-3 times per week, and finally increasing with 4-7 times per week. Similarly, there was a haphazard relationship between duration of use and risk of ovarian cancer, as estimates increased at 4-12 years, then decreased at 13-30 years and decreased further at >30 years reported exposure.

Pike et al.<sup>40</sup> in 2004 conducted a case-control study of women in Los Angeles County with histologically confirmed ovarian cancer or borderline tumors identified by the Cancer Surveillance Program between 18 and 74 years of age from 1992 to 1998. Controls were identified using a systematic algorithm based on the address of the patient. Participants were interviewed in person using a questionnaire covering medical and personal lifestyle history. Genital area talc usage was associated with a statistically significant increase in risk of ovarian cancer (OR: 1.60; 95% CI: 1.18-2.18) after adjustment for ethnicity, age, education, family history of ovarian cancer, tubal ligation, BMI, parity, age at last childbirth, number of births, number of incomplete pregnancies, oral contraceptive use, menopausal status, age at menopause and estrogen-progesterone therapy.

Jordan et al.<sup>41</sup> in 2007 reported a case-control study of women aged 18-79 years with histologically confirmed invasive and borderline ovarian cancer in Australia identified by the Australian Ovarian Cancer Study and state-based cancer registries between 2002 and 2005. Women with benign mucinous tumors were also identified by the Australian Ovarian Cancer Study and through records from three major pathology laboratories. Controls were randomly selected from the Australian Electoral Roll after stratifying for age and state. Participants were asked to complete and return a health and lifestyle questionnaire. Neither moderate talc use in the perineal region (OR: 0.4; 95% CI: 0.1-2.0) nor substantial talc use in the perineal region (OR: 1.0; 95% CI: 0.4-2.1) was associated with a statistically significant increase in risk of invasive mucinous ovarian cancer after adjustment for age, education level, parity, use of oral contraceptives, hysterectomy, tubal ligation and smoking status.

Gates et al.<sup>42</sup> in 2008 reported a nested case-control study of talc use, variants in the GSTM1, GSTT1 and NAT2 genes, and the risk of ovarian cancer using cases from the New England Case-Control Study (NECC) and the Nurses' Health Study (NHS). The "NECC questionnaires included multiple questions about regular use of talcum, baby or deodorizing powder as an adult. Specific questions were asked about type of use (as a dusting powder to the genital area, sanitary napkins, underwear or non-genital areas), frequency of use, age at first use, number of years used and brand of powder used. The 1982 NHS questionnaire requested information on whether the participant had ever commonly applied talcum, baby

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<sup>40</sup> Pike et al., *Hormonal factors and the risk of invasive ovarian cancer: a population-based case-control study*. (2004) 82(1) Fertil Steril. 186.

<sup>41</sup> Jordan SJ, Green AC, Whiteman DC, Webb PM, Australian Ovarian Cancer Study Group. *Risk factors for benign, borderline and invasive mucinous ovarian tumors: epidemiological evidence of a neoplastic continuum?* (2007) 107(2) Gynecol Oncol 223.

<sup>42</sup> Gates et al., *Talc use, variants of the GSTM1, GSTT1, and NAT2 genes, and risk of epithelial ovarian cancer*. (2008) 17(9) Cancer Epidemiol Biomarkers 2436.

or deodorizing powder to the perineal area (no, <once/week, 1-6 times/week or daily) or to sanitary napkins (yes/no).” There was a statistically significant increase in the risk of ovarian cancer with regular genital talc use in participants from the NECC study (OR: 1.62; 95% CI: 1.26-2.09) but no statistically significant increase in risk of ovarian cancer with regular talc use in the NHS (OR: 1.48; 95% CI: 0.82-2.68). Similarly, there was a statistically significant increase in the risk of ovarian cancer with daily genital talc use in participants from the NECC study (OR: 1.61; 95% CI: 1.18-2.2) but no statistically significant increase in risk of ovarian cancer with regular talc use in the NHS (OR: 1.34; 95% CI: 0.65-2.76). Regular genital talc use was associated with a statistically significant increase in risk of ovarian cancer using the combined study population (OR: 1.36; 95% CI: 1.14-1.63) after adjustment for duration of oral contraceptive use, parity, tubal ligation, BMI and duration of hormone replacement therapy. There was no clear dose-response with regard to frequency of genital talc use, with estimates falling with less than once a week usage and then rising with 1-6 times a week and daily usage.

Merritt et al.<sup>43</sup> in 2008 reported the Australian Ovarian Cancer Study, which was an Australia-wide case-control study of epithelial ovarian cancer. Cases were women diagnosed with invasive or low malignant potential ovarian cancer aged 18 to 79 years between 2002 and 2005. Controls were selected from the Australia Electoral Roll. Study participants filled out a comprehensive health and lifestyle questionnaire. “To determine use of talcum powder in the perineal region, participants were asked whether they had ever used powder or talc in the genital area or on underwear or sanitary pads/diaphragm. They were asked their age at first use and years of talc use in these areas.” Ever perineal use of talcum powder was associated with a statistically significant increase in risk of ovarian cancer (OR: 1.17; 95% CI: 1.01-1.36) after adjusting for age, education, parity and oral contraceptive use. However, there was no clear dose-response relationship, with a random shape of the exposure-response curve between perineal use of talcum powder and risk of ovarian cancer as well as the risk of cancer subtypes.

Moorman et al.<sup>44</sup> in 2009 reported a case-control study of epithelial ovarian cancer conducted in a 48-county region of North Carolina between 1999 and 2008. Cases were identified through the North Carolina Cancer Registry and were confirmed histopathologically. Controls were obtained from the same geographic region through random digit dialing. In-person questionnaires were administered, which included questions on medical history and lifestyle factors, including talc ever use. There was no statistically significant increase in risk of ovarian cancer with ever talc use among both white women (OR: 1.04; 95% CI: 0.82-1.33) and African Americans (OR: 1.19; 95% CI: 0.68-2.09) after adjusting for age.

In 2009, Wu et al.<sup>45</sup> conducted a case-control study of residents of Los Angeles County between the ages of 18 and 74 who had histologically confirmed invasive or

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<sup>43</sup> Merritt et al., *Talcum Powder, chronic pelvic inflammation and NSAIDs in relation to risk of epithelial ovarian cancer*. (2008) 122 Int’l J. Cancer 170.

<sup>44</sup> Moorman et al., *Ovarian Cancer Risk Factors in African-American and White Women*. (2009) 170(5) Am J Epidemiol 598.

<sup>45</sup> Wu et al., *Markers of inflammation and risk of ovarian cancer in Los Angeles County*. (2009) 124 Int’l J. Cancer 1409.

borderline ovarian cancer diagnosed from 1998 through 2002. Cases were identified by the Cancer Surveillance Program. Controls were identified using a neighborhood recruitment algorithm. Participants were interviewed using a questionnaire that covered medical, gynecological, reproductive and lifestyle history. To determine use of talcum powder, subjects were asked if they ever used talc at least once per month for six months or more. If the response was positive, participants were asked if “they had ever used talc in nonperineal areas (feet, arms, chest or back), perineal areas, or on underwear or sanitary pads/diaphragm,” as well “frequency of use (times per month) and years of talc use.” Ever talc use was associated with a statistically significant risk of ovarian cancer (OR: 1.48; 95% CI: 1.15-1.91) as was talc applied to the perineal area (OR: 1.53; 95% CI: 1.13-2.09) after adjusting for race/ethnicity, age, education, tubal ligation, family history of breast/ovarian cancer, menopausal status, use of oral contraceptives and parity. A statistically significant increase in risk of ovarian cancer was also seen in those who used talc for more than 20 years and more than 30 times per month (OR: 2.08; 95% CI: 1.34-3.23) and in those who had more than 52,000 talc uses (OR: 1.99; 95% CI: 1.34-2.96).

Rosenblatt et al.<sup>46</sup> in 2011 reported a case-control study of women from a 13-county area of Washington State who were 35 to 74 years old and who were diagnosed with invasive or borderline epithelial ovarian tumor between 2002 and 2005. Cases were identified through the Cancer Surveillance System and controls were selected by random digit dialing. In-person interviews were performed, and obtained information on demographic and lifestyle characteristics, medical history and obstetrical history. For powder use on sanitary napkins and deodorant spray, investigators recorded the total number of months of use. For the use of powder on the perineum after bathing, only intervals of at least one year when powder was usually used was recorded. Women were also asked to report the “types of powder(s) used after bathing, including talcum, baby, cornstarch, deodorant, body/bath, and other or unknown. The extent of exposure to perineal powder after bathing was assessed as lifetime duration of use . . . and as the estimated lifetime number of applications.” There was no statistically significant increase in the risk of ovarian cancer for using powder after bathing (OR: 1.27; 95% CI: 0.97-1.66) after adjusting for age, calendar year of diagnosis/reference date, county of residence, number of full-term births and duration of hormonal contraception.

Kurta et al.<sup>47</sup> in 2012 conducted a case-control study using data from the Hormones and Ovarian Cancer Prediction (HOPE) study. Cases were residents of Western Pennsylvania, Eastern Ohio and Western New York State and had histologically confirmed ovarian, peritoneal or fallopian tube cancers diagnosed between 2003 and 2008. Controls were frequency matched and identified through random digit dialing. Trained interviewers collected questionnaire data that included medical history and information about lifestyle. “Perineal talc use was defined as ever using dusting powder or deodorizing spray on the genital or rectal areas, on sanitary napkins, on underwear, or on diaphragms or cervical caps.” Perineal talc use was associated with a statistically significant increase in risk of ovarian cancer (OR: 1.40; 95% CI: 1.16-1.69) after adjusting for age and education.

<sup>46</sup> Rosenblatt et al., *Genital powder exposure and the risk of epithelial ovarian cancer*. (2011) 22 Cancer Causes Control 737.

<sup>47</sup> Kurta et al., *Use of Fertility Drugs and Risk of Ovarian Cancer: Results from a U.S.-Based Case-Control Study*. (2012) 21(8) Cancer Epidemiol Biomarkers Prev. 1282.

Terry et al.<sup>48</sup> in 2013 reported on a pooled analysis of case-control studies using data from the Ovarian Cancer Association Consortium. Investigators used data from eight case-control studies and included 8,525 cases of ovarian, fallopian tube or peritoneal cancer and 9,859 controls. Genital powder use was defined as “any type of powder (talc, baby, deodorizing, cornstarch, or unspecified/unknown) applied directly or indirectly (by application to sanitary pads, tampons, or underwear) to the genital, perineal, or rectal area.” Criteria for regular use varied between studies from “ever use” to “one year or longer.” “Women who reported both genital and non-genital powder use were classified as genital users.” Genital use of powder was associated with a statistically significant increase in risk of ovarian cancer when compared with no powder use (OR: 1.24; 95% CI: 1.15-1.33) after adjusting for age, oral contraceptive use, parity, tubal ligation history, BMI and race/ethnicity.

Wu et al.<sup>49</sup> in 2015 reported a case-control study of women with newly diagnosed histologically confirmed invasive epithelial ovarian cancer identified through the Cancer Surveillance Program. Cases were non-Hispanic white, Hispanic, or African American women aged 18 to 74 diagnosed between 2003 and 2008. In-person interviews were conducted using questionnaires, which included questions on demographics, lifestyle, medical history, family history and genital talc use. Results are based on pooling of four case-control studies in Los Angeles County investigating invasive epithelial ovarian cancer. Genital talc use was associated with a statistically significant increase in risk for invasive ovarian cancer in all study participants (OR: 1.46; 95% CI: 1.27-1.69); non-Hispanic whites (OR: 1.41; 95% CI: 1.21-1.67) and Hispanics (OR: 1.77; 95% CI: 1.20-2.62), but not in African Americans (OR: 1.56; 95% CI: 0.80-3.04). Every five years of talc use was also associated with a statistically significant increase in risk for invasive ovarian cancer in non-Hispanic whites (OR: 1.14; 95% CI: 1.08-1.21) and Hispanics (OR: 1.18; 95% CI: 1.02-1.36), but not in African Americans (OR: 1.15; 95% CI: 0.90-1.47). Estimates were adjusted for menopausal status, age at menarche, hormone therapy use, BMI, income, education, parity, oral contraceptive use, tubal ligation, endometriosis and family history of ovarian cancer.

Schildkraut et al.<sup>50</sup> in 2016 reported a case-control study of women enrolled in the African American Cancer Epidemiology Study from 11 locations in the United States. Cases included African American women aged 20 to 79 with newly diagnosed ovarian cancer. Controls were African American women who were identified through random digit dialing. Participants completed a baseline telephone interview, which includes questions on demographics, medical history and information on lifestyle. “[P]articipants were asked whether they had ever regularly used talc, cornstarch, baby, or deodorizing powders. Participants were considered ‘regular users’ if they reported using any of these powders at least one time per month for at least six months, and ‘never users’ if they did not. Regular users were asked about their frequency and duration of use, age at first use, and whether

<sup>48</sup> Terry et al., *Genital Powder Use and Risk of Ovarian Cancer: A Pooled Analysis of 8,525 Cases and 9,859 Controls*. (2013) 6(8) *Cancer Prev Res* 811.

<sup>49</sup> Wu et al., *African Americans and Hispanics Remain at Lower Risk of Ovarian Cancer Than Non-Hispanic Whites after Considering Nongenetic Risk Factors and Oophorectomy Rates*. (2015) 24(7) *Cancer Epidemiol Biomarkers Prev*. 1094 (“Wu 2015”).

<sup>50</sup> Schildkraut (2016).



they applied powders to genital areas (including on underwear or sanitary napkins, or on birth control devices like diaphragms) and/or nongenital areas.” There was a statistically significant increase in the risk of ovarian cancer with any genital use of powder (OR: 1.44; 95% CI: 1.11-1.86) after adjusting for age at diagnosis/interview, study site, education, tubal ligation, parity, BMI, duration of oral contraceptive use, first-degree family history of breast or ovarian cancer and interview year. In addition, as discussed above, when investigators stratified by the interview date, there was no statistically significant association between ovarian cancer and any genital use of body powder if the interview date was before 2014 (OR: 1.19; 95% CI: 0.87-1.63), but if the interview date was after 2014, there was a statistically significant increase in risk of ovarian cancer with any genital use of body powder (OR: 2.91; 95% CI: 1.70-4.97), after adjusting for the same potential confounders.

Cramer et al.<sup>51</sup> in 2016 reported a pooled analysis of case-control studies of women residing in Eastern Massachusetts and New Hampshire diagnosed with ovarian cancer between the ages of 18 and 80 using data from the NHS and several sites from the Ovarian Cancer Association Consortium. Controls were identified through random digit dialing. Participants “were asked whether they ‘regularly’ or ‘at least monthly’ applied powder to the genital or rectal area, sanitary napkins or tampons, underwear, or areas other than the genital-rectal area. Additional details included type of powder, age begun, years used, and applications per month. Lifetime exposure was estimated by multiplying frequency of application per month by months used.” This was divided by 360 to yield talc-years, which were divided into separate quartiles for dose-response analysis. Any genital powder use was associated with a statistically significant increase in the risk of ovarian cancer (OR: 1.33; 95% CI: 1.16-1.52) after adjusting for reference age, study center and study phase. There was no clear pattern suggesting a dose-response effect, with a random sine wave pattern with increasing risk, then decreasing risk, then increasing risk with total genital talc applications.

#### ***D. Cohort Studies***

Gertig et al.<sup>52</sup> reported the relationship between perineal talc use and ovarian cancer using participants from the NHS. This is a prospective study of 121,700 registered nurses in the United States who were ages 30-55 years at enrollment in 1976. Talc exposure was not evaluated when the study began, but questions regarding talc exposure were added in 1982. 78,630 women completed the questions regarding talc at baseline and formed the cohort for analysis and were followed for 14 years (1982-1996). There were 307 women who were subsequently diagnosed with ovarian cancer. After adjusting for confounders, no statistically significant association was found with ever talc use, with a relative risk for ovarian cancer of 1.09 (95% CI: 0.86-1.37) when compared to never talc use. Similarly, no statistically significant association was found with daily talc use, with a relative risk of 1.12 (95% CI: 0.82-1.55) when compared with never talc after adjusting for age, parity, duration of oral contraceptive use, BMI, tubal ligation, smoking status and postmenopausal hormone use. There was an increase in risk of invasive serous ovarian cancer, with a relative risk of

<sup>51</sup> Cramer et al., *The Association Between Talc Use and Ovarian Cancer: A Retrospective Case-Control Study in Two US States*. (2016) 27(3) Epidemiology 334.

<sup>52</sup> Gertig et al., *Prospective Study of Talc Use and Ovarian Cancer*. (2000) 92 J. Nat. Cancer Inst. 249.



1.40 (95% CI: 1.02-1.91) among ever talc users when compared to never talc users after adjusting for the same potential confounders.

Gates et al.<sup>53</sup> examined the association between ovarian cancer risk factors and ovarian cancer by histological subtype in the NHS and Nurses' Health Study II (NHSII). This prospective study included 221,866 women who completed baseline and biennial follow-up providing information on lifestyle factors and disease diagnoses. Follow-up was longer than the Gertig study and was 24 years in the NHS (1982-2006) and six years in the NHSII. There were 924 women who subsequently developed ovarian cancer and 721 cases with the histologies of interest (496 serous invasive, 139 endometrioid, 86 mucinous). Information on regular talc use was collected in 1982 and available for NHS participants only (108,870 women). No statistically significant increases in risk were found between talc used greater than once weekly with all epithelial (RR: 1.06; 95% CI: 0.89-1.28), serous invasive (RR: 1.06; 95% CI: 0.84-1.35), endometrioid (RR: 1.06; 95% CI: 0.66-1.69), or mucinous (RR: 1.5; 95% CI: 0.84-2.66) ovarian cancer when compared with less than once weekly talc use after adjusting for age, BMI, activity level, parity, breastfeeding, oral contraceptive use, tubal ligation, age at menopause, estrogen use, menopause status, smoking status and family history of breast or ovarian cancer.

Houghton et al.<sup>54</sup> assessed the perineal powder use and the risk of ovarian cancer prospectively in the Women's Health Initiative observational cohort, which enrolled postmenopausal women aged 50-79 from 40 clinical centers across the United States from 1993 to 1998 through 2012. Participants completed annual questionnaires to obtain information on risk factors and outcomes, including ovarian cancer. Perineal powder was assessed via self-report at baseline by asking participants if they had ever used powder on their private parts (genital areas). Those who answered yes were asked questions regarding duration of use. Participants were also asked about use with diaphragms and sanitary napkins or pads. There were 61,576 women who completed baseline questionnaires and followed for a mean 12.4 years. There were 429 women who subsequently developed ovarian cancer. No statistically significant increase in risk of ovarian cancer between ever powder use on genitals (HR: 1.12; 95% CI: 0.92-1.36) and never powder use on genitals was found after adjusting for age, race, duration of oral contraceptive use, duration of hormone replacement therapy, family history, age at last birth, BMI, smoking status, tubal ligation and parity. There was also no statistically significant increase in risk from duration of use between talc use greater than 10 years (RR: 0.98; 95% CI: 0.75-1.29) or greater than 20 years (RR: 1.10; 95% CI: 0.82-1.48) when compared with never talc use after adjusting for the same potential confounders. Similarly, no statistically significant increase in risk was found for all serous (RR: 1.16; 95% CI: 0.88-1.53), serous invasive (RR: 1.13; 95% CI: 0.84-1.51), mucinous (RR: 1.03; 95% CI: 0.47-2.27), or endometrioid (RR: 1.29; 95% CI: 0.64-2.61) ovarian cancer between ever talc use and never talc use after adjusting for the same potential confounders.

<sup>53</sup> Gates et al., *Risk Factors for Epithelial Ovarian Cancer by Histologic Subtype*. (2010) 171 Am. J. Epidemiology 45.

<sup>54</sup> Houghton et al., *Perineal Powder Use and Risk of Ovarian Cancer*. (2014) 106(9) J Nat. Cancer Inst.

Gonzalez et al.<sup>55</sup> evaluated the effect of douching and talc use on the risk of ovarian cancer prospectively in the Sister Study, which enrolled women aged 35 to 74 who had never had breast cancer and who had a sister or half-sister diagnosed with breast cancer in the United States and Puerto Rico from 2003 to 2009 through 2014. Participants completed computer-assisted telephone interviews, which included questions about lifestyle factors and health conditions. Participants also completed a self-administered questionnaire about personal products used in the 12 months prior to enrollment, which included questions about frequency of douching as well as talc use, method of talc use, and frequency of talc use. There were 50,884 women who completed questionnaires and, after excluding participants who had bilateral oophorectomies or ovarian cancer before enrollment or who had no follow-up information, 41,654 women were followed for a median of 6.6 years. There was no statistically significant increased risk of ovarian cancer (HR: 0.73; 95% CI: 0.44-1.2) with ever talc use during the 12 months prior to the study when compared with never talc use after adjusting for race, BMI, parity, duration of oral contraceptive use, baseline menopausal status and tubal ligation. There was, however, a statistically significant increase in risk of ovarian cancer (HR: 1.9; 95% CI: 1.2-2.9) with douching/no talc use when compared with neither use as well as an increased risk of ovarian cancer with douching in the past 12 months (HR: 1.8; 95% CI: 1.2-2.8) when compared with never douching after adjustment for the same potential confounders. This study highlights the potential for douching to be a confounder in previous investigations, and all but one study failed to control for the potential confounding effect of douching and risk of ovarian cancer.

### *E. Summary Of Observational Studies*

Evaluating the association between talc use and ovarian cancer in case-control studies poses several challenges that require attention. The assessment of exposure is difficult because it is solely based on self-report. Talc purchasing and use are not documented in the medical records or available in pharmacy records. As there is no reliable method of confirming talc usage, the accuracy and validity of these studies even under perfect circumstances can be dramatically affected by reporting bias. Additionally, the quantification of talc exposure is very difficult and may be impossible to verify accurately. Powders have varying amounts of talc and can be applied by various methods, leading to more or less exposure. There is no standardized dose/amount that is used, and there is no standard quantification method with verification that has been universally employed among the studies in the medical literature. Various studies collected information on the reported use of talc, diaphragm with talc, diaphragm storage only, all over body talc, genital talc, legs only talc, not genital talc, talcum powder in the perineum, talcum powder on sanitary pads, talcum powder on diaphragms, after bathing only, baby powder only, deodorizing powder, dusting powder to the perineum, any dusting powder, talc around the abdomen/perineum, perineal dusting, genital powder application, genital/rectal talc, powder to genitals, powder to diaphragm, or powder to sanitary napkins. As such, there are no case-control or cohort epidemiologic studies or meta-analyses that have investigated the effect of a standardized amount of talc usage or a standardized method of use to ensure consistency of the assessment of exposure. In addition, only a few epidemiologic studies have found any dose-response relationship between genital talc use and ovarian cancer.

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<sup>55</sup> Gonzalez (2016).

Furthermore, as in all case-control studies, recall bias is also of great concern. This arises from the phenomenon that cases are more likely than controls to think about and remember past exposures. Recall bias leads to differential misclassification of exposure and a falsely elevated estimate of risk between talc exposure and ovarian cancer. This is especially important if an exposure such as talc appeared in the news or was discussed in the public arena as having a possible causative association with ovarian cancer. There is evidence to suggest that hospital-based case-control studies are less likely to be subject to recall bias than population-based case-control studies because the degree to which study subjects think about possible past exposure is more similar (given that both cases and controls are being hospitalized).<sup>56</sup>

In general, cohort studies provide more evidence for a causal relationship between exposure and outcome and can often study many exposure-outcome relationships with less chance for bias and confounding than case-control studies if the design, conduct, data collection and analysis are proper. However, cohort study designs also remain susceptible to certain types of bias and confounding, and cohort studies are often very expensive, take a long time to conduct, and may be difficult to perform, especially if the outcome of interest is rare.

Plaintiffs' epidemiologists repeatedly downplay the results of the four relevant cohort studies. Dr. McTiernan, for example, has the opinion that there are a number of "serious limitations" in the cohort studies, including that they were not specifically designed to investigate the relationship between talc use and ovarian cancer, but rather examined a number of different outcomes.<sup>57</sup> This point is irrelevant as cohort studies are designed specifically to have the ability to investigate many exposure-outcome relationships, even if the cohort study was not specifically designed to look at the exposure-outcome relationship of interest. Dr. McTiernan also criticizes the cohort studies on other grounds – that they did not obtain detailed lifetime histories of talcum powder use and therefore could not measure dose-response; that the sample sizes were too small to detect a relative risk like 1.24; and that the latency period of ovarian cancer makes these studies "not likely reflective of risk from exposure to talcum powder products."<sup>58</sup> But as just explained, no type of study in this context can provide an accurate measure of dose-response due to the problems inherent in relying on study participants' subjective assessments regarding the amount of talcum powder they use, and as I elaborate in part VIII.A below, Dr. McTiernan's criticisms with respect to latency and sample size are speculative and wrong. All of this suggests that Dr. McTiernan's criticisms reflect her own bias. While cohort studies also have their own limitations like any other study design, the focused criticism of cohort studies by plaintiffs' epidemiologists, even though they are generally considered more reliable than case-control studies, suggests a biased approach to their analyses.

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<sup>56</sup> Oleckno, *Epidemiology: Concepts and Methods*. (2008) at 207; Infante-Rivard, *Hospital or Population Controls for Case-Control Studies of Sever Childhood Diseases?* (2003) 157(2) Am J Epidemiol 176.

<sup>57</sup> McTiernan Report 46.

<sup>58</sup> *Id.* at 46-47.

## F. Meta-Analysis

Gross et al.<sup>59</sup> in 1995 reviewed nine case-control studies (all previously described above) and one cohort study to evaluate the association between talc and ovarian cancer. The authors combined the results of seven studies and found an increase in risk of ovarian cancer (RR: 1.20; 95% CI: 1.01-1.44) with any talc exposure, and combined the results of five studies and, after adjustment, found an increase in risk of ovarian cancer (RR: 1.29; 95% CI: 1.02-1.63). Unfortunately, there is little detail provided regarding the methods used to identify, evaluate and analyze the studies, making the interpretation of this investigation challenging and problematic. In addition, all of the limitations described above with respect to the included case-control studies remain inherent within this investigation.

Huncharek et al.<sup>60</sup> in 2003 evaluated 15 case-control studies (all previously described above) and one cohort study using a predefined technique for literature search, study inclusion and analysis. The study included data from 11,933 subjects and pooling all subjects demonstrated a summary OR of 1.33 (95% CI: 1.16-1.45) for ovarian cancer with being exposed to never versus ever talc, none versus any talc and never versus any talc. Seven studies analyzed together yielded an inverse relationship between duration of exposure and ovarian cancer, with low-exposure groups having a higher risk and high-exposure groups having a lower risk, demonstrating a lack of clear dose-response. Hospital-based case-control studies demonstrated no significant relationship between talc use and risk of ovarian cancer (RR: 1.19; 95% CI: 0.99-1.41), while population-based case-control studies showed an increased risk of ovarian cancer with talc use (RR: 1.38; 95% CI: 1.25-1.52). As mentioned above, the limitations of the previously described case-control studies remain inherent within this review. Furthermore, differences in recall bias between hospital-based and population-based case-control studies provide one possible explanation for differences found between the two different study designs.

Huncharek et al.<sup>61</sup> in 2007 evaluated nine case-control studies (all previously described above) investigating the association between talc via dusting of contraceptive diaphragms and ovarian cancer in 2,281 cases of ovarian cancer and 3,608 controls using a predefined technique for literature search, study inclusion and analysis. Pooling all subjects demonstrated no significant risk of ovarian cancer with being exposed to talc via dusting of contraceptive diaphragms (OR 1.03; 95% CI: 0.80-1.37). One included case-control study did not explicitly provide data on talc use via contraceptive diaphragms, and without data from this study, the resultant OR was 1.12 (95% CI: 0.84-1.48).<sup>62</sup>

<sup>59</sup> Gross & Berg, *A meta-analytical approach examining the potential relationship between talc exposure and ovarian cancer*. (1995) 5(2) J Expo Anal Environ Epidemiol. 181.

<sup>60</sup> Huncharek et al., *Perineal Application of Cosmetic Talc and Risk of Invasive Epithelial Ovarian Cancer: A Meta-analysis of 11,933 Subjects from Sixteen Observational Studies*. (2003) 23 Anticancer Res. 1955.

<sup>61</sup> Huncharek et al., *Use of cosmetic talc on contraceptive diaphragms and risk of ovarian cancer: a meta-analysis of nine observational studies*. (2007) 18 Eur J Cancer Prev 422.

<sup>62</sup> Dr. Zambelli-Weiner has criticized the Huncharek studies and did indeed find some errors in them. However, her analysis did not show that any errors materially affected the conclusions of these studies.

Langseth et al.<sup>63</sup> in 2008 reported on a meta-analysis of 20 case-control studies and make reference to one cohort study. Results were separated into 14 population-based case-control studies and six hospital-based case-control studies. The investigators state that the cohort study showed “no association between cosmetic talc use and risk of all subtypes of ovarian cancer combined,” although the results were not shown. The hospital-based case-control studies reported a pooled odds ratio of 1.12 (95% CI: 0.92-1.36) and the population-based case-control studies reported a pooled odds ratio of 1.40 (95% CI: 1.29-1.52). The combined OR from all case-control studies using a fixed effects model was 1.35 (95% CI: 1.26-1.46). This meta-analysis reflects some methodological weaknesses, including the fact that there is no report of a literature search strategy and no structured review of the literature for eligible studies.

Berge et al.<sup>64</sup> in 2018 reported on a meta-analysis of 27 studies, which included 24 case-control studies and three cohort studies. The authors reported a “small increased risk” with a summary relative risk of 1.22 (95% CI: 1.13-1.30) for ever talc use and ovarian cancer, but found that the cohort studies did not show an association (RR 1.02 (95% CI: 0.85-1.20)). The investigators demonstrated that given the total number of exposed and unexposed cases of ovarian cancer, the statistical power of the cohort studies to detect a relative risk difference of 1.25 was 0.99, which matched that of the case-control studies, and thus rejected inadequate power as an explanation for the lack of an association between talc exposure and ovarian cancer in the cohort studies and the heterogeneity between study designs. The study found a “weak trend in RR with duration and frequency of genital talc use,” but cautioned that this analysis was based on few studies and that the “modest association between both duration and frequency of use of talc may reflect a true relationship, or recall bias or confounding.” The authors noted that several aspects of their analysis, including heterogeneity between case-control and cohort studies, did “not support a causal interpretation of the association.”

Penninkilampi et al.<sup>65</sup> in 2018 reported on a meta-analysis of 24 case-control studies and three cohort studies. The study reported a summary odds ratio of 1.31 (95% CI: 1.24, 1.39) for any talc use and ovarian cancer, but this association was not present in cohort studies (OR 1.06 (95% CI: 0.90-1.25)). Although the study reported a statistically significant association in the cohort studies for serous invasive ovarian cancer (OR 1.25 (95% CI: 1.01, 1.55)), it excluded the 2010 Gates study from its analysis. The study further found that more than 3,600 lifetime talc applications “were slightly more associated with ovarian cancer than” fewer than 3,600 lifetime applications (odds ratios of 1.42 and 1.32, respectively), but noted that these data came from case-control studies and were therefore “prone to recall bias” (which the study observed could be particularly problematic due to recent media coverage of talc lawsuits). It also observed that the “mechanism by which perineal talc use may increase the risk of ovarian cancer is uncertain,” and in particular that use of NSAIDs “is not inversely associated with the incidence of ovarian cancer, as may be

<sup>63</sup> Langseth et al., *Perineal use of talc and risk of ovarian cancer*. (2008) 62 J Epidemiol Community Health 358.

<sup>64</sup> Berge et al., *Genital use of talc and risk of ovarian cancer: a meta-analysis*. (2018) 27 Eur J Cancer Prev 248.

<sup>65</sup> Penninkilampi and Eslick, *Perineal Talc Use and Ovarian Cancer: A Systematic Review and Meta-Analysis*. (2018) 29(1) Epidemiology 41.



expected if the etiology was related to chronic inflammation.” The authors cited the “substantial need for further research on a potential mechanism” as one reason why a causal relationship could not be established with any certainty.

In summary, the published meta-analyses have been of varying quality and in general observed a weak association (odds ratio roughly 1.3) between talc use and ovarian cancer. However, as the meta-analyses have noted, the observed increased risk is restricted entirely to case-control studies and may be a result of bias and/or confounding. Although different studies employ different techniques to attempt to adjust for these issues, meta-analyses are only as good as their underlying studies, and the fact that the meta-analyses themselves combine studies that used different adjustment approaches can exacerbate issues regarding overall reliability.

## VII. ANALYSIS OF STUDIES

It is my opinion that there is insufficient evidence to support a causal association between exposure to talc and risk of ovarian cancer based on the body of available epidemiologic observational studies that have been performed and reported in the literature. While there is no single method for undertaking a causal assessment based on epidemiology, the criteria formulated by Austin Bradford Hill are often used and are considered the gold standard for evaluating causation once an association has been identified. These include: strength of association, consistency, specificity, temporality, biologic gradient, plausibility, coherence, experimentation and analogy.<sup>66</sup> While Bradford Hill suggests nine different viewpoints to consider in a careful examination of the association between exposure and outcome before concluding that a causal relationship exists, it is important to understand that none of his concepts provide unquestionable evidence for or against a causative relationship and none is required as essential or absolutely necessary. They can simply help to provide a framework to guide epidemiologists to decide whether or not there is another more likely way of explaining the association, including non-causal explanations for the results of individual studies. These other explanations can come from bias, confounding and/or random error (as discussed above), can lead to risk estimates that are falsely higher or lower than actual risk and can even lead to conclusions that an exposure causes disease when it does not.

Even before starting such an analysis, however, one should examine whether the epidemiologic literature establishes a true association – the fundamental predicate of a Bradford Hill analysis. As Hill noted in his seminal article setting forth his epidemiologic approach, before evaluating causation, studies must “reveal an association between two variables, *perfectly clear-cut and beyond what we would care to attribute to the play of chance*.”<sup>67</sup> As I discuss further below, this requirement is likely not satisfied here because we are not presented with a “clear cut” association.

A number of the Hill factors further weigh decidedly against a causal finding in this instance. In particular, and as detailed in this section, lack of consistent results among studies, lack of reliable assessment of exposure to talc, lack of a dose-response relationship

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<sup>66</sup> Hill, *Environment and disease: association or causation?* (1965) 58 Proc Royal Soc Med. 295.

<sup>67</sup> *Id.*



and lack of strength of association all contribute to my opinion that there is a lack of reliable evidence to conclude that exposure to talc increases the risk of ovarian cancer.

***A. Lack Of Consistency Between Studies***

One of the most striking aspects of the studies is their inconsistency.

Some studies demonstrate an association between talc use and ovarian cancer, while others do not. As set forth in the table below, there are seven hospital-based case-control studies that consistently demonstrate no statistically significant association between exposure to talc and risk of ovarian cancer. There are four cohort studies that also consistently demonstrate no statistically significant association between exposure to talc and risk of ovarian cancer. There are 26 population-based case-control studies that demonstrate inconsistent results, with some studies demonstrating a statistically significant association between exposure to talc and risk of ovarian cancer, while others demonstrate no statistically significant association between exposure to talc and risk of ovarian cancer. This lack of consistency in finding a statistically significant association between talc use and risk of ovarian cancer likely arises from several factors. The studies use varying questionnaires, describe varying self-reported assessments of talc exposure and varying self-reported assessments of frequency and duration of talc use, and apply no adjustment or varying levels of adjustment for potential confounders. Finally, each one of these observational studies has limitations (recall bias and confounding in case-control studies; lack of repeated measure of exposure in cohort studies). The consistency of effect between hospital-based case-control studies and the cohort studies is somewhat assuring and the heterogeneity among population-based case-control studies weigh against finding a causal relationship between exposure and outcome. In addition, even though the methods for at least two of the reported meta-analyses were relatively robust, the studies that were used in all of the meta-analyses were of limited quality.

***B. Lack Of Reliable Assessment Of Talc Exposure***

In all of the studies investigating the possible causal association between talc and ovarian cancer, assessment of talc exposure relies on self-report. Talc use is not documented in a medical record or in a pharmacy record in order to confirm, or at least verify, self-reported use. This has a substantial potential to lead to recall and reporting bias, in particular in case-control studies, although this type of bias may also be present in cohort studies. Furthermore, self-reported exposures were obtained from responses to questionnaires on the use of talc or talc products, including: use of talc, diaphragm with talc, diaphragm storage only, all over body talc, genital talc, legs only talc, non-genital talc, talcum powder in the perineum, talcum powder on sanitary pads, talcum powder on diaphragms, “genital fiber use”, after bathing only, baby powder only, deodorizing powder, dusting powder to the perineum, any dusting powder, talc around the abdomen/ perineum, perineal dusting, genital powder application, genital/rectal talc, powder to genitals, powder to diaphragm, or powder to sanitary napkins. Varying amounts of talc exist within different powders, varied methods can be used to apply talc either by spray or by powder, varying amounts may be applied on diaphragms, and the amount applied may be very different depending on the method of application and the person applying it. Questions arise, such as: How much talc is used in dusting? How much talc is used in the perineum? How much

talc is used after bathing only, etc.? In addition, there are no observational studies or meta-analyses that have investigated the effect of a standardized amount of talc usage or a standardized method of use to ensure consistency of the assessment of exposure. As an epidemiologist, I find this lack of ability to quantify a dose to be a gaping hole in the exposure-outcome relationship and a tremendous limitation in all of the epidemiologic studies evaluating talc and risk of ovarian cancer.

### ***C. Lack Of A Dose-Response To Talc Exposure***

There have been very few case-control studies and no cohort studies that have reported a dose-response relationship between talc exposure and risk of ovarian cancer; and measures of dose-response generally have varied widely among studies.

Dose-response curves may increase with increasing exposure (i.e., increased risk of heart disease with increasing level of cholesterol) and decrease with increasing exposure (i.e., decreased risk of heart disease with increased doses of cholesterol lowering agent). Typically, a dose-response curve that depicts an increased risk would demonstrate increasing risk with increasing quantity of exposure, increasing frequency of exposure, increasing duration of exposure or a combination. When the curve is concave, convex or has a haphazard random shape, that is a red flag to epidemiologists. Studies that have evaluated the potential for dose-response have found: (1) random or “sine wave” (up and down) risk<sup>68</sup>; (2) convex (up then down) risk<sup>69</sup>; (3) concave (down then up) risk<sup>70</sup>; and (4) even decreasing risk<sup>71</sup> with either increasing frequency or duration of talc use. Studies by Wu<sup>72</sup> and Cramer<sup>73</sup> demonstrated increasing risk of ovarian cancer with increasing frequency and duration of reported talc use, but not all cut-offs were statistically significant. Only one study<sup>74</sup> demonstrated a statistically significant association between duration of reported talc use (per five years of reported genital talc use) and risk of ovarian cancer in Hispanics (OR: 1.18; 95% CI: 1.02-1.36) and non-Hispanic whites (OR: 1.14; 95% CI: 1.08-1.21).

In sum, the vast majority of both case-control and cohort studies demonstrate no statistically significant dose-response relationship between talc use and risk of ovarian cancer.

### ***D. Lack Of Strength Of Association***

Another indicator of causality is strength of association.

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<sup>68</sup> Booth (1989); Wong (1999); Cook (1997); Mills (2004); Merritt (2008); Gertig (2000).

<sup>69</sup> Cramer (1999); Chang (1997); Cramer (2016); Rosenblatt (2011); Houghton (2014).

<sup>70</sup> Whittemore (1988); Gates (2008).

<sup>71</sup> Hartge (1983).

<sup>72</sup> Wu (2009).

<sup>73</sup> Cramer (2016).

<sup>74</sup> Wu (2015).

Relative risk and odds ratios are two measures of strength of association. The higher the relative risk or odds ratio, the greater the likelihood that the relationship is causal. For instance, the International Primary Pulmonary Hypertension Study was a case-control study where cases were defined as patients with pulmonary hypertension without a known reason.<sup>75</sup> Controls were randomly selected from lists of consecutive patients seen by the same general practitioner. Each participant went through a face-to-face interview and was asked about demographics, medical and surgical history as well as medication history. Use of appetite suppressants was associated with a statistically significant increase in risk of pulmonary hypertension (OR: 6.3; 95% CI: 3.0-13.2) after adjusting for systemic hypertension, use of cocaine or intravenous drugs, smoking status, BMI, weight loss behavior, use of thyroid extracts and possible exposure to anorexic agents. The odds ratio in this study was found to be 6.3, and with a relative risk this high it is unlikely that any other factor could be the cause of the association.

The higher the relative risk or odds ratio, the less likely other factors can explain the association. Similarly, for relative risks or odds ratios that are lower, it is important to understand that there may be factors other than the exposure of interest that can explain the association. Rosenblatt (1998)<sup>76</sup> found a statistically significant association between women who had ever douched and those who used powder in the perineal area (OR: 2.9; 95% CI: 1.6-5.1). Gonzalez et al.<sup>77</sup> as described above evaluated the effect of douching and talc use on the risk of ovarian cancer prospectively in the Sister Study. Results demonstrated no statistically significant increased risk of ovarian cancer (HR: 0.73; 95% CI: 0.44-1.2) with ever talc use when compared with never talc use after adjusting for confounders. However, there was a statistically significant increase in risk of ovarian cancer (HR: 1.9; 95% CI: 1.2-2.9) with douching/no talc use when compared with neither use as well as a statistically significant increase in risk of ovarian cancer with douching in the past 12 months (HR: 1.84; 95% CI: 1.2-2.8) when compared with never douching. As previous studies (except for Harlow et al. (1992)) did not account for douching, the relatively weak statistically significant associations could potentially be explained by confounding. One explanation could be that since talc users are more likely to douche and douching appears to increase risk of ovarian cancer, previous studies may not have captured the correct exposure (douching) in the causal pathway and mistakenly concluded talc to be the exposure that increased risk of ovarian cancer instead of douching. Similarly, it is also possible that the relatively weak yet statistically significant associations seen in some of the case-control studies could be explained by other potential confounders that were only considered in some of the studies or that have not yet even been identified.

In summary, based on evidence in the literature and the lack of consistency across studies, the lack of a reliable assessment of actual talc exposure, the lack of a significant dose-response to talc exposure, and a weak strength of association between a poorly characterized exposure to talc and risk of ovarian cancer, it is impossible to conclude that talc exposure increases the risk of ovarian cancer.

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<sup>75</sup> Abenhaim et al., *Appetite-Suppressant Drugs and the Risk of Primary Pulmonary Hypertension*. (1996) 335(9) N Engl J Med 609.

<sup>76</sup> Rosenblatt (1998).

<sup>77</sup> Gonzalez (2016).

Author	Odds Ratio/Relative Risk/Hazard Ratio	95% CI	Statistically Significant Association?
<b>Hospital-based case-control studies</b>			
Hartge et al. (1983)	0.70	0.04-1.10	No
Whittemore et al. (1988)	1.45	0.81-2.60	No
Booth et al. (1989)	1.30	0.80-1.90	No
Rosenblatt et al. (1992)	1.70	0.70-3.90	No
Tzonou et al. (1993)	1.05	0.28-3.98	No
Hartge and Stewart (1994)	0.30 (5-9 years of talc exposure) 0.50 (10+ years)	0.10-1.40 0.20-1.50	No
Wong et al. (1999)	1.13	0.88-1.44	No
<b>Population-based case-control studies</b>			
Cramer et al. (1982)	1.92	1.27-2.89	Weak
Harlow and Weiss. (1989)	1.10	0.70-2.10	No
Harlow et al. (1992)	1.50	1.00-2.10	Weak
Chen et al. (1992)	3.90	0.90-10.6	No
Cramer and Xu (1995)	1.60	1.20-2.10	Weak
Purdie et al. (1995)	1.27	1.04-1.54	Weak
Green et al. (1997)	1.30	1.10-1.60	Weak
Shushan et al. (1996)	1.97	1.06-3.66	Weak
Chang and Risch (1997)	1.42	1.08-1.86	Weak
Cook et al. (1997)	1.60	0.90-2.80	No
Godard et al. (1998)	2.49	0.94-6.58	No
Cramer et al. (1999)	1.60	1.18-2.15	Weak
Ness et al. (2000)	1.50	1.10-2.00	Weak
Mills et al. (2004)	1.37	1.02-1.85	Weak
Pike et al. (2004)	1.60	1.18-2.18	Weak
Jordan et al. (2007)	1.00	0.40-2.10	No
Gates et al. (2008)	1.36	1.14-1.63	Weak
Merritt et al. (2008)	1.17	1.01-1.36	Weak
Moorman et al. (2009)	Afr. Am.: 1.19 Caucasian: 1.04	Afr. Am: 0.68-2.09 Caucasian: 0.82-1.33	No
Wu et al. (2009)	1.53	1.13-2.09	Weak
Rosenblatt. (2011)	1.27	0.97-1.66	No
Kurta et al. (2012)	1.40	1.16-1.69	Weak
Wu et al. (2015)	1.46	1.27-1.69	Weak
Schildkraut et al. (2016)	1.44	1.11-1.86	Weak
<b>Pooled case-control studies</b>			
Terry et al. (2013)	1.24	1.15-1.33	Weak

Author	Odds Ratio/Relative Risk/Hazard Ratio	95% CI	Statistically Significant Association?
Cramer et al. (2016)	1.33	1.16-1.52	Weak
<b>Cohort studies</b>			
Gertig et al. (2000)	1.09	0.86-1.37	No
Gates et al. (2010)	1.06	0.89-1.28	No
Houghton et al. (2014)	1.12	0.92-1.36	No
Gonzalez et al. (2016)	0.73	0.44-1.20	No

## VIII. METHODOLOGICAL FLAWS IN PLAINTIFFS' EXPERTS' EPIDEMIOLOGY-BASED OPINIONS

I was asked to address whether the causation analyses set forth in the expert reports of plaintiffs' epidemiology experts were conducted in a scientifically reliable manner. As set forth below, I have concluded that there are several significant methodological flaws that are prevalent in multiple plaintiffs' experts' reports, rendering their analyses unreliable.

### A. *Disregard For The Hierarchy Of Evidence*

The hierarchy of evidence is well-established within the scientific community.<sup>78</sup> Consistent with that hierarchy, epidemiologists consider meta-analyses of multiple randomized clinical trials, followed by individual randomized clinical trials, as the strongest evidence to support a causal relationship between an exposure and an outcome. These are followed by the observational designs, with cohort studies, case-control studies, and cross-sectional studies in descending order also providing potential evidence for a causal association between exposure and outcome. The lowest quality of evidence comes from case reports, case series and other descriptive studies. As a general rule, lower-quality studies provide less information on whether a causal relationship exists than studies of higher quality.

Although this hierarchy should not be indiscriminately applied to all research questions and studies, an epidemiologist should provide sound scientific justifications for departing from these well-established norms. For example, a poorly designed and conducted meta-analysis or randomized clinical trial may provide less evidence than a well-designed and conducted cohort or case-control study.

A number of plaintiffs' epidemiologists ignore the well-established hierarchy of evidence in their reviews of the relevant human studies, either by treating all studies equally or, even more troublingly, placing an inappropriate amount of weight on case-control studies that they claim demonstrate a weak association between talc use and ovarian cancer, while ignoring stronger, better designed cohort studies that do not show any association and also better capture the temporal nature that must exist to demonstrate a causal relationship

<sup>78</sup> Nat. Health & Medical Res. Council, *NHMRC Levels of Evidence and Grades for Recommendations for Developers of Clinical Practice Guidelines* (2009).

between exposure and outcome. For example, Dr. Moorman states the following in her report:

As I evaluated individual epidemiologic studies (case-control and cohort studies) that described the risk for ovarian cancer associated with talc use, I did not weight one design more heavily than the other because there are advantages and disadvantages to each design for evaluating talc as a cause of ovarian cancer.<sup>79</sup>

Likewise, Dr. McTiernan states in her report that “all” studies provide evidence of causal effect.<sup>80</sup> When asked at her deposition about the hierarchy of scientific evidence, Dr. McTiernan testified that she was “not sure what hierarchy” the questioner was referring to and that, in any event, “depending on the question, one type of study could be preferable to another, but in general all of the studies provide information, and we look at the totality of evidence.”<sup>81</sup> When I teach students about study design in epidemiology, this is exactly what I tell them *not* to do. When evaluating whether causality can be demonstrated from a particular study or series of studies, it is essential to evaluate the strengths and potential weaknesses of each individual study. Because case-control studies are more easily subject to biases and confounding factors and can often not fully capture the temporal relationship between exposure and outcome, as discussed in detail below, they are often less reliable than cohort studies.

Even more problematic than treating all studies the same is plaintiffs’ experts’ tendency to place *more* emphasis on case-control studies than higher-quality cohort studies, despite their limitations. For example, despite her disclaimer of adherence to any hierarchy of evidence, Dr. McTiernan does apply a hierarchy of her own, suggesting that case-control studies are preferable in situations where an exposure is “very difficult to measure and which can change over time.”<sup>82</sup> While I agree with her that case-control studies are often “easier” when an exposure may be “difficult to measure,”<sup>83</sup> a poor-quality case-control study does not provide higher quality data due to limitations in design. Furthermore, case-control studies, as mentioned above, can be subject to bias and confounding, even when they are well designed. Even though case-control studies sometimes may be “easier” to conduct, the temporal relationship between exposure and outcome is often more difficult to establish because ascertainment of the exposure is done after the outcome. Finally, it is often extremely difficult for a case-control study design to accurately investigate an exposure that changes over time and a cohort design will more likely be able to investigate time varying exposures than a case-control study design. Dr. McTiernan’s suggestion therefore is illogical, and in my opinion, is not supported by any science.

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<sup>79</sup> Moorman Report 10.

<sup>80</sup> McTiernan Report 18.

<sup>81</sup> McTiernan Deposition 118.

<sup>82</sup> McTiernan Deposition 117.

<sup>83</sup> *Id.*



Dr. McTiernan has also criticized the multiple cohort studies finding no association between talc use and ovarian cancer on the ground that those studies involved an “insufficient number of cases . . . to find a statistically significant result.”<sup>84</sup> Dr. McTiernan’s criticism seems to be that, because ovarian cancer has a low incidence rate – and so few study participants developed the disease in both the study and control populations – the studies cannot rule out the possibility of a link between talc use and ovarian cancer. This position is incorrect.

The first problem with Dr. McTiernan’s criticism is that her focus on the low overall incidence of ovarian cancer in the population is misplaced. Incidence rates reported by the National Cancer Institute’s Surveillance, Epidemiology, and End Results (SEER) Program are estimated rates for *all* women. These rates may change from year to year, and rates may be different for different age groups and races as reported by SEER.<sup>85</sup> Observational studies do not study the population at large, but rather a subset of the population (i.e., study participants). And the incidence of ovarian cancer in the population enrolled in the cohort studies, including Gonzalez (2016) (41,654 women),<sup>86</sup> Houghton (2014) (61,576 women),<sup>87</sup> and Gates (2010)/Gertig (2000) (108,870 women),<sup>88</sup> was higher than in the general population, with 429 cases among 68,435 participants who reported exposure to talc, and 943 cases among 141,345 participants who reported no exposure to talc. It is not surprising that the incidence rates of ovarian cancer in the cohort studies are much higher than the reported rates for all females by the SEER Program because the cohort studies may include women who are in general at higher risk of developing ovarian cancer (i.e., older age, family history of cancer etc.).

A higher incidence of disease in the study population means that the number of participants needed to detect true risk is decreased – i.e., smaller sample sizes can detect the same amount of risk. Thus, because the cohort studies involve women who likely have a higher risk of ovarian cancer than the general population as reported by SEER, the study sample sizes needed to detect a given difference in risk between groups will be smaller. (This is why epidemiologists study higher-risk groups for less-common disease.) Specifically, using the Berge study’s meta-analysis of cohort studies,<sup>89</sup> which concluded that combined cohort studies yielded no increased risk of ovarian cancer when comparing participants exposed to talc to participants not exposed to talc (RR: 1.02; 95% CI: 0.85-1.20), I calculated that the incidence of ovarian cancer and the overall number of study participants was sufficient to detect a true risk of ovarian cancer of 1.25 with a power of .99.<sup>90</sup> In other words, there would be a 1% chance of being incorrect and concluding that there is no difference in risk of ovarian cancer between participants exposed and unexposed to talc if there was a true increase in risk of ovarian cancer with talc exposure.

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<sup>84</sup> McTiernan Deposition 124.

<sup>85</sup> <https://seer.cancer.gov/statfacts/html/ovary.html>.

<sup>86</sup> Gonzalez (2016).

<sup>87</sup> Houghton (2014).

<sup>88</sup> Gates (2010); Gertig et al., *Prospective Study of Talc Use and Ovarian Cancer*. (2000) 92 J. Nat. Cancer Inst. 249.

<sup>89</sup> Berge 2018.

<sup>90</sup> Calculations performed with STATA SE 15.1, StataCorp, College Station, TX.

Dr. Moorman's power-based criticisms are similarly flawed. She relies on commentary by Narod,<sup>91</sup> who states that "the lack of a significant overall association between ever use of talc and ovarian cancer in the cohort studies may be due to the fact that despite the large size of the cohorts, the studies were not adequately powered to detect a relative risk of approximately 1.2." But this commentary rests on sample size calculations with certain assumptions regarding risk of ovarian cancer, including the same incidence rate issue that undermines Dr. McTiernan's critique. When the actual incidence rate of ovarian cancer in the cohort studies is taken into account, it decreases the study sample size needed to the sample sizes reported in the relevant cohort studies.

Relatedly, the fact that so few participants in Gonzalez (2016),<sup>92</sup> Houghton (2014),<sup>93</sup> and Gates (2010)/Gertig (2000),<sup>94</sup> developed ovarian cancer regardless of their talc exposure does not undermine the validity of these studies. To the contrary, it demonstrates that the risk of developing ovarian cancer is small among the higher-risk populations that were studied, and that talc exposure simply does not increase that risk to a statistically significant degree.

Other plaintiffs' experts have criticized cohort studies on the grounds that they do not sufficiently account for the latency period of ovarian cancer. For example, Dr. Siemiatycki has stated that the "short follow-up periods in cohort studies would be a source of bias."<sup>95</sup> According to Dr. Siemiatycki, because cohort study researchers "collect information about exposure, and then follow [patients] for two years to find out how many of them got cancer, and whether there is a difference between the people who were exposed and the people who are not exposed, well, that would be pretty hopeless because it takes more than two years for cancers to develop and be diagnosed."<sup>96</sup> But this supposed limitation on cohort studies is greatly exaggerated. Houghton (2014) asked about talcum powder use in study participants who had been followed for up to 18 years and found no statistically significant increased risk in ovarian cancer.<sup>97</sup> Gates (2010) added to the Gertig (2000) cohort and followed study participants for up to 24 years and found no statistically significant elevations in risk for talc use for all epithelial ovarian cancers.<sup>98</sup> Similarly, Gonzalez (2016) followed participants with a sister or half-sister with a history of breast cancer for a median 6.5 years and found no association between the use of talc and ovarian cancer.<sup>99</sup> In any event, the women followed in all of these studies presumably did not start

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<sup>91</sup> Narod, *Talc and ovarian cancer*. (2016) 141 Gynecol. Oncol. 410. Plaintiffs' experts Drs. Ellen Blair Smith and Judith Wolf place similar reliance on Narod's commentary on the power of cohort studies to detect risk. (Blair Smith Rep. at 20; Wolf Rep. at 6.)

<sup>92</sup> Gonzalez (2016).

<sup>93</sup> Houghton (2014).

<sup>94</sup> Gates (2010); Gertig et al., *Prospective Study of Talc Use and Ovarian Cancer*. (2000) 92 J. Nat. Cancer Inst. 249.

<sup>95</sup> Siemiatycki Deposition 171.

<sup>96</sup> *Id.*

<sup>97</sup> Houghton (2014).

<sup>98</sup> Gates (2010); Gertig (2000).

<sup>99</sup> Gonzalez (2016).

using talc for the first time the day the studies began and therefore would have had longer durations of use than the time period of the study – in most cases many years more.

***B. Ignoring Or Minimizing The Effects Of Recall Bias And Other Biases In Case-Control Studies***

Recall bias is of particular concern in retrospective case-control studies because, as compared to controls, cases “tend to search their memories to identify what might have caused their disease; healthy controls have no such motivation.”<sup>100</sup> This, in turn, tends to artificially increase the supposed effect of the exposure. As Vetter and Mascha point out, a number of factors can affect recall bias.<sup>101</sup> Study participants with a particular disease tend to “search their memories to identify what might have caused their disease,” whereas “healthy controls have no such motivation.”<sup>102</sup> Cases tend to remember past exposures more than controls, and cases are often more likely than controls to investigate whether certain risk factors increase the risk of developing a certain disease. In addition, individuals with a disease may have greater awareness of potential risk factors for their condition or may have become sensitized by repeated physician interviews. Consider again the previous example of the investigator who is trying to determine if there is a relationship between sugary drinks and high blood pressure. If the cases tend to recall and report more sugary drink consumption simply because they have reflected more on their past experiences, recall bias could result in differential misclassification and a false overestimation of the measure of risk between the sugary drinks and high blood pressure. Because cases and controls have different incentives to recall past exposures, recall bias can lead to finding associations between exposures and diseases that do not exist. As I explained earlier, the Schildkraut case-control study demonstrates an excellent example of the effect of recall bias in assessing the effects of genital talc use before and after the year 2014. Dr. Singh attempts to minimize this finding because “there was a statistically significant increased risk both before and after 2014.”<sup>103</sup> This is incorrect, as there is only a statistically significant association between any genital body powder use and ovarian cancer in interviews conducted after 2014, providing an exceptional real-world example of the possibility of recall bias in a case-control epidemiologic study. Likewise, Dr. McTiernan asserts that recall bias is “unlikely” to be an issue because the studies for which data collection pre-dated news reports of this association showed similar effects to those for which data were collected afterward.<sup>104</sup> However, there is no reason to believe that recall bias did not affect cases reporting perineal talc use before 2014, since there were reports of an association in the medical literature (and presumably, the media) prior to that time – and the tendency in a case-control study for cases to remember past exposures more than controls is an issue that affects case-control studies regardless of date.

<sup>100</sup> Grimes & Schultz, *Bias and causal associations in observational research*. (2002) 259(9302) Lancet 248.

<sup>101</sup> Vetter & Mascha, *Bias, Confounding, and Interaction: Lions and Tigers, and Bears, Oh My!*. (2017) 125(3) Anesth Analg 1042.

<sup>102</sup> Grimes & Schultz (2002).

<sup>103</sup> Singh Report 45-46.

<sup>104</sup> McTiernan Report 24.

Dr. Siemiatycki also states that if recall bias were present, “we would systematically see elevated RRs from case-control studies for all manner of variables in all kinds of studies.”<sup>105</sup> This makes little epidemiologic sense, as recall bias is a known particular concern in retrospective studies that use a case-control design to investigate the association between exposure and outcome.<sup>106</sup>

### *C. Jumping To Causation Without Sufficiently Determining Association*

Epidemiologists and other researchers are often asked to determine whether an exposure can cause an illness. As noted above, the Bradford Hill factors supply the commonly used framework for undertaking such an analysis. But as also noted above, the existence of a clear-cut, statistically significant association is a prerequisite to such an analysis. One needs to find an association between exposure and outcome first, and it is not acceptable epidemiologic methodology to apply the Bradford Hill criteria in the absence of an established association.

Plaintiffs’ experts have the opinion that “most” or the “vast majority” of the epidemiological studies show an increased relative risk of ovarian cancer for genital talc users. For example:

Dr. Moorman states that, “among the more than two dozen studies that have reported on the association between talc use and ovarian cancer, the vast majority of them reported relative risks or odds ratios greater than one[.]”<sup>107</sup>

Dr. Singh concludes that “[m]ost case control studies demonstrate an increased risk factor of ovarian cancer associated with talc use with an OR between 1.3 and 1.6, even after adjusting for various risk factors.”<sup>108</sup>

Dr. Smith-Bindman pronounces that her “review of case-control studies on talcum powder use and ovarian cancer risk were consistent and indicate a 50% increase in risk of serous invasive cancer related to routine talcum powder exposure compared to no exposure.”<sup>109</sup>

The table in Section VII demonstrates that none of the hospital-based case-control studies, none of the cohort studies, and nearly half of the population-based case-control studies found no statistically significant association. Given that the association found in the literature is far from “perfectly clear-cut,” it is not clear to me that a Bradford Hill analysis is even appropriate in this situation.

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<sup>105</sup> Siemiatycki Report 54.

<sup>106</sup> Schultz & Grimes (2002).

<sup>107</sup> Moorman Report 15.

<sup>108</sup> Singh Report 53.

<sup>109</sup> Smith-Bindman Report 34 (emphasis omitted).

#### ***D. Methodological Problems With Dr. Smith-Bindman's Meta-Analysis***

One of plaintiffs' epidemiologists, Dr. Smith-Bindman, conducted her own, new meta-analysis of a portion of the talc literature for purposes of this litigation. There are significant problems with her approach that render it unreliable. The first is that the rationale for a new non-peer-reviewed meta-analysis – in an area that has already been subject to repeated meta-analyses on substantially the same body of literature – is not clearly stated. “Although this subject has hardly been studied, repeating or updating rarely (9%) leads to changes in the pooled results of meta-analyses.”<sup>110</sup> Therefore, while repeated meta-analyses should not be “discouraged a priori,” an “important question” is the “rationale for repeating the analysis” and, where the results differ from prior studies, another important question is “how [the] authors defend their conclusions in relation to prior studies.”<sup>111</sup> Dr. Smith-Bindman does not adequately do this; nor does she subject this new meta-analysis to any form of peer review – one of the cornerstones of the body of evidence contained in the medical literature. Under a section of her report that is supposed to set forth a “rationale” for her new meta-analysis, she fails to explain the methodological shortcomings of prior meta-analyses.<sup>112</sup> Instead, she asserts that she believes that “the most important research question to answer in this review is whether regular exposure to talcum powder is associated with ovarian cancer” – and serous cancer particularly – and thus that her review should be limited to those studies that supply data for “as close to approximately daily” use of talcum powder as possible.<sup>113</sup> But she does not explain why daily use is the right metric. Nor, in any event, does she actually limit her review to daily use, which, as she acknowledges, is not specifically examined in all of the studies she included in her review; and at the same time, she also excluded studies that did address daily use based on her own (unexplained) assessment that their “research methods were poorly defined.”<sup>114</sup>

Dr. Smith-Bindman reports an odds ratio of 1.43 for all ovarian cancers that is somewhat higher than prior meta-analyses,<sup>115</sup> and ultimately that the association is indicative of a causal relationship.<sup>116</sup> She does not explain why these results might be more valid and defensible in relation to prior meta-analyses, which report somewhat lower odds ratios and reach the opposite conclusion on causation. The sum total of her discussion on this is that “[t]he existing systematic reviews (in particular Penninkilampi and Berge) also concluded a significant increase in ovarian cancer risk following talcum powder exposure,”<sup>117</sup> but she fails to acknowledge that the odds ratios were lower and that neither study embraced a causal conclusion in its review of the overall scientific literature. This omission is critical. Scientists do not practice in a vacuum; they must take into account the

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<sup>110</sup> Vavken & Dorotka, *A Systematic Review of Conflicting Meta-Analyses in Orthopaedic Surgery*. (2009) 467(10) Clin Orthop Relat Res. 2723.

<sup>111</sup> *Id.*

<sup>112</sup> Smith-Bindman Report 30.

<sup>113</sup> *Id.* at 31.

<sup>114</sup> *Id.* at 32.

<sup>115</sup> *Id.* at 33.

<sup>116</sup> *Id.* at 41.

<sup>117</sup> *Id.* at 34.

entire existing body of scientific evidence. Dr. Smith-Bindman's failure to do so in any meaningful sense, as well as her failure to state the fact that there are no studies that investigated a standardized dose of talc, a standardized method of exposure to talc, or a validated assessment of the frequency and duration of talc usage, makes this a pointless exercise. Because of these fundamental flaws in her study, there is no valid basis to accept her unique perspective over the body of work of many other investigators over several decades that has reached the opposite conclusion.

A second problem with Dr. Smith-Bindman's approach concerns her treatment of serous ovarian cancer specifically. Dr. Smith-Bindman claims to have found data concerning serous ovarian cancer specifically from four studies.<sup>118</sup> But such post-hoc analyses are often speculative because identifying subgroups after the fact can be subject to problems associated with confounding. Therefore, while these analyses may be hypothesis-generating, caution is advised in interpreting the results. For instance, if weight, socioeconomic status, race or douching each were causally related to the risk of serous ovarian cancer and also related to the use of talc but were not investigated in the post-hoc analysis because the study was not designed to look at these factors, then investigators may conclude there is an association when one does not in reality exist between talc use and serous ovarian cancer.

Identifying subgroups after the fact is also inherently prone to bias because of the investigator's impressions of the results of the study.<sup>119</sup> Essentially, it allows the researcher to start with a conclusion and work backwards, which is exactly the opposite of the scientific method. And even setting aside the bias concerns in such a backwards endeavor, findings from post-hoc analyses may also be spurious because the study was not designed to address questions that are developed post-hoc, and thus, for example, no effort would have been made to match cases and controls within the subgroup.

Dr. Smith-Bindman's meta-analysis has other methodological flaws as well. For instance, Dr. Smith-Bindman stated that she alone performed "the search, according – obtaining all the papers, and then reviewing the bibliography of all those papers."<sup>120</sup> Most meta-analyses of higher quality involve more than one investigator to perform the search to decide what studies to include and what studies not to include in order to avoid bias. This was not done.<sup>121</sup> She also states that Dr. Hall helped her with "abstracting the data as a second set of eyes and in doing the statistical summary."<sup>122</sup> Based on her deposition, there also appear to be discrepancies between the numbers reported in Dr. Smith-Bindman's meta-analysis and those from the published literature, and she testified that she "was struggling to understand why the numbers and the figures were not exactly the same as the ones . . . in the published manuscript."<sup>123</sup> Dr. Smith-Bindman, as she stated in her

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<sup>118</sup> *Id.*

<sup>119</sup> Wang et al., *Statistics in Medicine – Reporting of Subgroup Analyses in Clinical Trials*. (2007) 357(21) N Engl J Med 2189.

<sup>120</sup> Smith-Bindman Deposition (Vol. I) 101.

<sup>121</sup> *Id.*

<sup>122</sup> *Id.*

<sup>123</sup> Smith-Bindman Deposition (Vol. II) 255-56.



deposition, called Dr. Hall in between the first and second part of her deposition to ask Dr. Hall “to clarify how she did the calculations of the numbers that are shown in the figures.”<sup>124</sup> These irregularities further call her meta-analysis into question.

### ***E. Methodological Errors In Plaintiffs’ Epidemiologists’ Bradford Hill Analyses***

Once an association has been established, Bradford Hill set forth a framework to help assess whether a causal relationship exists: strength of association, consistency, specificity, temporality, biologic gradient, plausibility, coherence, experimentation, and analogy. To the extent a Bradford Hill analysis is even called for, plaintiffs’ experts took an irregular approach that seems to be results-driven. In my discussion below, I focus on three criteria – strength of association, consistency of association and biologic gradient – that are the most relevant to my opinions and experience as an epidemiologist.

#### ***1. Plaintiffs’ epidemiologists find a “strong” association where there is none.***

Strength of association measures the level of increased risk of developing a particular disease as a result of exposure to a particular substance. Strength of association is typically measured by calculating an odds ratio or relative risk – i.e., the ratio of the risk of disease in the population exposed to the risk of disease in those unexposed. A relative risk of 1.0 would indicate that there is no difference in disease risk between individuals exposed and those who are not. When the risk is low, epidemiologists typically require other strong evidence of causation.

Although there is no universal numeric definition of a “strong” association between exposure and outcome in terms of risk, it is generally accepted that ratios of risk measures between 1.1 and 2.0 represent a weak association between exposure and outcome in part because other factors (bias, confounding and random error) have the potential to explain away an apparent association of that level.<sup>125</sup> One after another, plaintiffs’ epidemiologists mischaracterize the – at best – weak association between talc use and ovarian cancer as one that is strong. For example:

Dr. Siemiatycki states that “[*such*] a *high and significant* [relative risk] could not have occurred by chance.”<sup>126</sup>

Dr. Singh writes that he “place[s] significant weight on the fact that studies demonstrate *a strong association* between talcum powder use and ovarian cancer[.]”<sup>127</sup>

Dr. Moorman concludes that, “[t]aken as a whole, the *overwhelming statistical strength of these studies*, whose results are replicated over decades across a wide

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<sup>124</sup> *Id.* 255.

<sup>125</sup> Wynder et al., *Radford Conference Report: Weak associations in epidemiology and their interpretation* (3rd ed.). (1982) 11 Prev. Med. 464.

<sup>126</sup> Siemiatycki Report 63 (emphasis added).

<sup>127</sup> Singh Report 63 (emphasis added).

variety of populations and investigators, further supported by consistent meta-analysis, weighs very heavily in favor of a causal inference.”<sup>128</sup>

In his own non-peer-reviewed meta-analysis, Dr. Siemiatycki calculated the relative risk as 1.28. While I agree with Dr. Siemiatycki that a summary relative risk of 1.28, in general, represents that an exposed group has a 28% increased risk of an outcome, a relative risk in this range is weak, and may well result from bias, confounding, and/or random error rather than a true causal relationship. There is simply no disagreement about this within the scientific community. Plaintiffs’ experts’ insistence that a 1.28 relative risk is “high” raises the concern that they are pursuing a results-driven approach to their causation analysis instead of proper scientific methodology.

Furthermore, Dr. Siemiatycki states that “the statistical significance of individual studies is irrelevant to the consideration of causality; it is the totality of evidence embodied in the meta-analysis that counts.”<sup>129</sup> This might be something to consider in an ideal setting where multiple studies exist to evaluate the effect of a certain exposure that had the same design, the same conduct and the same analysis. But in this instance, in evaluating the effect of talc exposure on the risk of ovarian cancer, one cannot simply ignore the results of individual studies by lumping them together, especially when the individual studies were very different in terms of design, conduct, and analysis.

## ***2. Plaintiffs’ experts fabricate consistency by ignoring inconsistent studies.***

Plaintiffs’ experts uniformly assert that the consistency criterion has been satisfied. Dr. Singh states, for example, that “the direction and strength of association of talc and ovarian cancer is generally consistent across studies.”<sup>130</sup> Dr. McTiernan likewise concludes that “the association between use of talcum powder products and risk of ovarian cancer was highly consistent.”<sup>131</sup> I would agree with plaintiffs’ experts that there are some consistencies among the studies, but those consistencies are among hospital-based case-control studies and among large cohort studies showing no statistically significant association between talc exposure and ovarian cancer. By contrast, there are inconsistencies between hospital-based and population-based case-control studies and within population-based case-control studies. As mentioned above, there are seven hospital-based case-control studies that demonstrate no statistically significant association between talc exposure and risk of ovarian cancer, while there are 26 population-based case-control studies that show inconsistent results, with some studies demonstrating a significant effect of talc exposure on risk of ovarian cancer and others showing no significant effect of talc exposure on risk of ovarian cancer. In addition, there are four cohort studies that also demonstrate no statistically significant association between talc exposure and risk of ovarian cancer. This lack of consistency both within and between study designs suggests that any association may result from bias, confounding, and/or random error, and therefore weighs against a causal relationship.

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<sup>128</sup> Moorman Report 29 (emphasis added).

<sup>129</sup> Siemiatycki Report 63.

<sup>130</sup> Singh Report 63.

<sup>131</sup> McTiernan Report 64.

Moreover, it is important to remember (contrary to the suggestion of several of plaintiffs' experts) that for this criterion to weigh in favor of finding a causal relationship, there must be a consistency in *statistically significant* associations. Consistency in relative risks that are not statistically significant is not meaningful because that sort of consistency does not provide any degree of confidence that the claim of association made by the study is more than random chance.

### 3. *Plaintiffs' experts claim there is a dose-response where none exists.*

A causal association is far more likely if there is demonstrated biological gradient – i.e., a dose-response such that a greater dose leads to a greater risk of disease incidence rate. Almost every epidemiological study has failed to show any dose-response relationship between genital talc use and ovarian cancer as described above.<sup>132</sup> Indeed, plaintiffs' own expert Dr. Siemiatycki acknowledged in 2008 that “[t]he main epidemiological evidence against the association [between talc use and ovarian cancer] is the absence of clear exposure-response associations in most studies[.]”<sup>133</sup>

In responding to this scientific consensus, plaintiffs' epidemiologists insist that the literature supports a finding of a dose-response relationship. For example, Dr. Siemiatycki has the opinion that “there is a clear indication of increasing risk with increasing cumulative exposure” in the Terry 2013 and Schildkraut 2016 studies.<sup>134</sup> But the Terry study – which Dr. Siemiatycki calls “the most important piece of evidence we have on dose-response”<sup>135</sup> – “observed no significant trend . . . in risk with increasing number of lifetime applications.”<sup>136</sup> A significant trend was found in that study only when non-users were included in the analysis. Including individuals who are not exposed to a substance in calculating a dose-response trend is inappropriate, however, because it renders this criterion redundant of the strength-of-association inquiry. Dr. Siemiatycki dismissed the fact that the p-value for the trend is not statistically significant by suggesting that “the absence of statistical significance of the trend among the four exposed subsets is not equivalent to the demonstration of an absence of dose-response.”<sup>137</sup> That is pure speculation; if the trend line cannot be shown to be statistically significant, then there is no way to tell whether an actual relationship exists. The Schildkraut study likewise only included findings on the difference in risk between, in essence, never-users and ever-users of talc, and its analysis is therefore not relevant to a dose-response relationship.

Indeed, determining the dose of talc exposure is problematic. As Dr. Moorman acknowledges, the relevant dose of talc is not the amount applied but the amount, if any,

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<sup>132</sup> Nat. Cancer Inst., *Ovarian, Fallopian Tube, and Primary Peritoneal Cancer Prevention (PDQ) – Health Professional Version*, [https://www.cancer.gov/types/ovarian/hp/ovarian-prevention-pdq#link/\\_220\\_toc](https://www.cancer.gov/types/ovarian/hp/ovarian-prevention-pdq#link/_220_toc) (last updated Jan. 4, 2019); Gonzalez (2016); Houghton (2014); Gates (2010).

<sup>133</sup> Langseth (2008).

<sup>134</sup> Siemiatycki Report 63.

<sup>135</sup> *Id.* at 45.

<sup>136</sup> Terry (2013).

<sup>137</sup> Siemiatycki Report 44.

that actually reaches the ovaries.<sup>138</sup> However, there is no validated method of evaluating the amount applied, let alone how much (if any) reaches the ovaries. As previously discussed, asking a woman how much talc she powdered on to the underwear is not something that can be objectively measured. Instead, it is inherently subjective and prone to inaccurate estimation. As also discussed above, this creates the potential for recall, reporting, and measurement bias, all of which can lead to false conclusions based on the results. For all of these reasons, the potential for inaccurate classification of exposure leads to tremendous limitations in the entire body of relevant literature, limiting the ability to conclude that there is a causal relationship between talc exposure and ovarian cancer.

## **IX. SUMMARY AND CONCLUSIONS ASSESSING CAUSALITY**

In designing an epidemiological study, the goal of a scientist is to derive findings that represent the truth in the population being studied. In this respect, choosing a study design that minimizes or eliminates the effects of bias and confounding is very important. In the context of assessing whether epidemiological studies indicate an association between genital talc use and ovarian cancer, recall bias is of particular concern among case-control studies and has demonstrably affected findings of association.

The methodologies used by plaintiffs' experts ignore fundamental principles of epidemiology. In particular, plaintiffs' experts ignore the hierarchy of evidence in evaluating studies and rely on study designs that are inherently susceptible to bias. Specifically, plaintiffs' experts pay particular attention to criticizing cohort studies, with little acknowledgment of the limitations in the case-control studies that find weak associations.

Plaintiffs' experts generally agree that even the studies that do show an association between talc use and ovarian cancer have found a relative risk in the range of 1.2-1.6. This, by definition, is a weak association. Plaintiffs' epidemiologists nonetheless characterize the association as "strong." Likewise, plaintiffs' epidemiologists try to demonstrate a dose-response relationship by relying on methodologically flawed studies and statistically insignificant trend lines. They also see consistency where the studies are inherently inconsistent.

As a professor of medicine and of public health, I have focused my career on using the science of epidemiology as a scientific tool to help improve our understanding of health and disease. The distortion of epidemiological science for purposes of litigation does not achieve those goals. Instead, it undermines scientific efforts to better understand the etiology of disease.

When analyzed in a methodological manner, the body of medical literature simply does not support the conclusion that perineal exposure to talc causes ovarian cancer.

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Moorman Report 30.

# APPENDIX A

Curriculum Vitae for Academic Promotion  
The Johns Hopkins University School of Medicine



Christian A. Merlo, M.D., M.P.H.

February 22, 2019

**DEMOGRAPHIC AND PERSONAL INFORMATION**

**Current Appointments**

2006-2015	Assistant Professor of Medicine, Johns Hopkins University School of Medicine
2009-2015	Assistant Professor of Epidemiology, Johns Hopkins University Bloomberg School of Public Health
2010-present	Associate Program Director for Scholarship, Osler House Staff Program, Johns Hopkins University School of Medicine
2014-present	Director of Outpatient Services, Johns Hopkins Division of Pulmonary and Critical Care Medicine
2015-present	Associate Program Director, Adult Cystic Fibrosis Center, Johns Hopkins Cystic Fibrosis Center
2015-present	Associate Professor of Medicine, Johns Hopkins University School of Medicine
2015-present	Associate Professor of Epidemiology, Johns Hopkins University Bloomberg School of Public Health

**Personal Data**

Division of Pulmonary and Critical Care Medicine  
Department of Medicine  
1830 E. Monument Street, 5<sup>th</sup> Floor  
Baltimore, MD 21205  
Phone: (410) 502-7044  
Fax: (410) 502-7048  
e-mail: cmerlo@jhmi.edu

**Education and Training**

Undergraduate

1992 A.B., Biology/Visual Arts, The College of The Holy Cross, Worcester, MA, *cum laude*

Doctoral/graduate

1996 M.D., Georgetown University School of Medicine, Washington, DC

2003 M.P.H., Johns Hopkins University Bloomberg School of Public Health, Baltimore, MD

Postdoctoral

1996-1997	Intern, Internal Medicine, Georgetown University School of Medicine, Washington, DC
1997-1999	Resident, Internal Medicine, Georgetown University School of Medicine, Washington, DC
1999-2000	Chief Resident, Internal Medicine, Georgetown University School of Medicine, Washington, DC
2000-2001	Clinical Fellow, Division of Pulmonary & Critical Care Medicine, Johns Hopkins University School of Medicine, Baltimore, MD
2001-2004	Research Fellow, Division of Pulmonary & Critical Care Medicine, Johns Hopkins University School of Medicine, Baltimore, MD

**Professional Experience:**

1999-2000 Instructor, Georgetown University School of Medicine, Washington, DC



2003-2004	Intensivist, Virginia Hospital Center, Arlington, VA
2004-2006	Instructor, Johns Hopkins University School of Medicine, Baltimore, MD
2006-2015	Assistant Professor, Johns Hopkins University School of Medicine, Baltimore, MD
2009-2015	Assistant Professor of Epidemiology, Department of Epidemiology, JHSPH
2015-present	Associate Professor, Johns Hopkins University School of Medicine, Baltimore, MD
2015-present	Associate Professor of Epidemiology, Department of Epidemiology, JHSPH

## RESEARCH ACTIVITIES

### Peer Reviewed Original Science Publications

1. Lechtzin N, John M, Irizarry R, **Merlo C**, Diette GB, Boyle MP. Outcomes of adults with cystic fibrosis infected with antibiotic-resistant *Pseudomonas aeruginosa*. *Respiration* 2006; 73: 27-33.
2. Wright JM, **Merlo CA**, Reynolds JB, Zeitlin PL, Garcia JG, Guggino WB, Boyle MP. Respiratory epithelial gene expression in patients with mild and severe cystic fibrosis lung disease. *Am J Respir Cell Mol Biol* 2006; 35: 327-336.
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#### Invited Reviews

1. **Merlo CA**, Boyle MP. Modifier genes in cystic fibrosis lung disease. J Lab Clin Med 2003;141:237-41.
2. **Merlo CA**, Orens JB. Candidate selection, overall results, and choosing the right operation. Semin Respir Crit Care Med 2010;31:99-107.
3. Braun AT, **Merlo CA**. Cystic fibrosis lung transplantation. Curr Opin Pulm Med 2011;17:467-72.
4. Kirk GD, **Merlo CA**, For the Lung HIV Study Group. HIV infection in the etiology of lung cancer: confounding, causality, and consequences. Proc Am Thorac Soc 2011;8:326-32.
5. Lambert AA, **Merlo CA**, Kirk GD. Human immunodeficiency virus-associated lung malignancies. Clin Chest Med 2013;34:255-72.

#### Inventions, Patents, Copyrights

- 2010 **Merlo CA**, Reh DR, Hoag JB. Method and severity scale for measuring epistaxis among patients with hereditary hemorrhagic telangiectasia (HHT). Used worldwide as a primary outcome in HHT interventional clinical trials.

#### Extramural Sponsorship (current, pending, previous)

##### Current Grants

- |                     |   |
|---------------------|---|
| 09/26/13 – 07/31/18 | <u>Immune Mechanisms of HIV-associated COPD</u><br>U01HL121814<br>NIH<br>\$505,539<br>PI: Gregory Kirk, MD PhD (Johns Hopkins School of Public Health)<br>Role: Co-I<br>0.60 calendar months<br>This proposal directly addresses critical gaps in our understanding of the clinical spectrum and consequences of HIV-associated COPD and will identify key biologic mechanisms contributing to the disease. Findings will inform the clinical management and development of interventions targeting HIV associated COPD, and may also inform broader strategies for COPD in non-HIV infected populations. |
| 07/01/14 – 06/30/19 | <u>Clinical Risk Factors for Primary Graft Dysfunction</u><br>R01HL087115<br>NIH subaward<br>\$19,984<br>PI: Jason Christie, MD (University of Pennsylvania)<br>Role: Co-I<br>0.12 calendar months<br>The major goal of this multicenter study is to define risk factors for the development of primary graft dysfunction following lung transplantation.   |
| 09/01/14 – 08/31/18 | <u>Predictors, consequences and mechanisms of accelerated lung aging in HIV</u><br>R01HL126549<br>NIH<br>\$499,997<br>PI: Gregory Kirk, MD PhD (Johns Hopkins School of Public Health)<br>Role: Co-I<br>0.60 calendar months<br>The goal of this program is to establish risk factors, associated co-morbidities, and immunologic and inflammatory biomarkers associated with accelerated decline in lung function in the SHIELD cohort of HIV-positive inner-city intravenous drug users.  |
| 07/01/15 – 06/30/18 | <u>Transition of Care for Patients with Cystic Fibrosis who Undergo Lung Transplantation</u><br>Spruance Foundation II Discovery Fund   |

\$300,000

PI: Christian Merlo, MD MPH

2.4 calendar months

The major goal of this proposal is to identify factors which may help to improve the process of lung transplantation for patients with cystic fibrosis.

#### Previous

07/01/03 – 06/30/04

Gene Expression Analysis of Nasal Respiratory Epithelial Cells in  $\Delta$ F508/ $\Delta$ F508 Individuals with Mild and Severe Cystic Fibrosis Lung Disease

Bauernschmidt Fellowship in Pulmonary Disease

Eudowood Foundation

\$35000

Role: PI

The goal of this study was to evaluate differences in gene expression between patients with cystic fibrosis with mild and severe lung disease.

07/01/04 – 06/30/07

The Effect of Multiple Antibiotic Resistant *Pseudomonas aeruginosa* on Outcomes in Cystic Fibrosis

The Harry Shwachman Clinical Investigator Award

Cystic Fibrosis Foundation

\$270000

Role: PI

6.0 calendar months

The goal of this study was to evaluate the impact of multiple antibiotic resistant *Pseudomonas aeruginosa* (MARPA) on outcomes among patients with cystic fibrosis.

07/01/06 – 06/30/07

Emphysema and HIV infection within the ALIVE cohort in Baltimore

Thomas and Carol McCann Innovative research Fund for Asthma and Respiratory Disease

\$35000

Role: Co-PI

The main goal of this study was to evaluate the association between emphysema and HIV infection among the ALIVE cohort in Baltimore.

01/01/08 – 12/30/12

The Study of HIV Infection in the Etiology of Lung Disease (SHIELD)

RFAHL07008

NIH

\$549,598

PI: Gregory Kirk, MD PhD (Johns Hopkins School of Public Health)

Role: Co-PI

0.60 calendar months

06/01/11 – 02/28/15

North American Study of Epistaxis in HHT (NOSE)

Hereditary Hemorrhagic Telangiectasia Foundation

\$11,126

Role: site PI

0.12 calendar months

This was a multicenter randomized placebo-controlled trial comparing bevacizumab, estrogen, tranexamic acid, and placebo in patients with HHT-related epistaxis.

09/06/12 – 06/30/14

Using mHealth to Respond Early to Acute Exacerbations of COPD in HIV mREACH

R34HL117349

NIH

\$376,291

PI: Gregory Kirk, MD PhD (Johns Hopkins School of Public Health)

Role: Co-I

0.60 calendar months



This clinical trial planning grant evaluated the feasibility, acceptability and defined optimal trial elements for an m-Health intervention to identify early exacerbations in HIV-COPD to improve management and clinical outcomes.

#### **Research Program Building / Leadership:**

- 2010-present Associate Program Director for Scholarship, Osler Residency Program, Johns Hopkins University School of Medicine. In my capacity, I am responsible for the research experience for the Osler House Staff throughout residency training. This involves one on one meetings to discuss research interests and goals, an online lecture series providing an introduction to research, pairing with faculty mentors, mentorship in the presentation of research projects at local and national meetings, collecting data highlighting scholarly activity, and reporting these data to the Director for internal use as well as for ACGME purposes.
- 2010-present Director of Research, The Johns Hopkins Lung Transplant Program. In my capacity, I am responsible for coordination of research efforts within the lung transplant program. This involves multidisciplinary projects spanning across many disciplines (Medicine, Surgery, Rehabilitation, Psychology, Epidemiology) as well as across different levels of training from faculty, fellows, residents, and medical students.
- 2010-2018 Director, Hereditary Hemorrhagic Telangiectasia Center of Excellence. In my capacity, I am responsible for the coordination of multicenter clinical trials as well as local investigations among patients with HHT. Our center was responsible for creation of an epistaxis severity score (HHT-ESS), the first objective measure of epistaxis severity, now used worldwide clinically as well as an outcome measure in HHT clinical investigations.
- 2016-present Associate Director, The Johns Hopkins Adult Cystic Fibrosis Program. In my capacity, I am responsible for the coordination of aspects of clinical and research coordination for our cystic fibrosis program.
- 2016-present Director of Research, The Johns Hopkins Adult Cystic Fibrosis Program. In my capacity, I am responsible for coordination of research efforts within the Adult CF program. This involves multidisciplinary projects spanning across many disciplines (Medicine, Surgery, Psychology, Epidemiology) as well as across different levels of training from faculty, fellows, residents, and medical students.

#### **EDUCATIONAL ACTIVITIES**

##### **Educational Publications**

**Peer-reviewed, original, educational publications – None**

**Review Articles – None**

**Editorials – None**

##### **Case Reports**

1. **Merlo CA**, Studer SM, Conte JV, Yang SC, Sonnett J, Orens JB. The course of neurofibromatosis type 1 on immunosuppression after lung transplantation: report of 2 cases. J Heart Lung Transplant 2004; 23: 774-776.
2. Houston B, Reiss KA, **Merlo C**. Healthy, but comatose. Am J Med 2011; 124: 303-305.

##### **Book and Book Chapters**

1. **Merlo CA**, Boyle MP. "Adult Cystic Fibrosis". In The Osler Medical Handbook. Mosby. Philadelphia: 60, 899-911, 2003.
2. **Merlo CA**, Terry PB. Concise Review: Diagnosis and management of pulmonary arteriovenous malformations. In Harrison's Online. 2002. <http://www.harrisonsonline.com>.
3. **Merlo CA**, Hansel N. "Have a working knowledge of EMTALA laws as they apply to the ICU. How to be a good referring and accepting ICU physician". In Avoiding Common ICU Errors. Lippincott. 2008.
4. **Merlo CA**. Critical Care Medicine. In First Aid for the Internal Medicine Boards. McGraw-Hill. New York: 16, 123-132, 2010.

5. **Merlo CA.** Pulmonary Medicine. In First Aid for the Internal Medicine Boards. McGraw-Hill. New York: 4, 553-580, 2010.
6. Dasenbrook EC, **Merlo CA.** "Cystic Fibrosis and Bronchiectasis". In Lung Transplantation. Informa. 2010.
7. Hayes M, **Merlo CA.** "Hemoptysis". The Principles and Practice of Hospital Medicine, 1<sup>st</sup> Edition, Sylvia C. McKean, Editor-in-Chief, McGraw-Hill publishers.
8. **Merlo CA.** "Diffuse Parenchymal Lung Disease." In Current Therapy in Thoracic and Cardiovascular Surgery. Mosby 2013.
9. **Merlo CA,** Terry PB. "Chest X-Ray Review". In The Johns Hopkins Internal Medical Board Review. Mosby. 2015

**Letters, correspondence** - None

**Other Media** - None

## **Teaching**

### **Classroom instruction**

- |              |   |
|--------------|---|
| 2003-2010    | Pulmonary physiology small group facilitator, Johns Hopkins University School of Medicine, Baltimore, MD.   |
| 2003-2010    | Pulmonary pathophysiology small group facilitator, Johns Hopkins University School of Medicine, Baltimore, MD.  |
| 2004-2010    | Good Samaritan Internal Medicine Program Guest Lectures – Cystic Fibrosis, Pulmonary Function Testing, Baltimore, MD.   |
| 2004-present | Lecturer, Carol Johns Service (Inpatient Pulmonary Service) – Lecture monthly about Cystic Fibrosis and Lung Transplantation to medical students, residents, and fellows as part of the core curriculum on the inpatient pulmonary service, Johns Hopkins University School of Medicine, Baltimore, MD. |
| 2004-present | Lecturer, Pulmonary and Critical Care Medicine Fellow's Core Conference – Cystic Fibrosis, Lung Transplantation, Hereditary Hemorrhagic Telangiectasia, and Noninfectious Pulmonary Complications of HIV, Johns Hopkins University School of Medicine, Baltimore, MD.                                   |
| 2006-2014    | Chest Radiography Conference Director – Lecture weekly for 10-15 Pulmonary and Critical Care Medicine fellows regarding the reading of chest radiographs and computed tomography, Johns Hopkins University School of Medicine, Baltimore, MD.   |

### **Clinical Instruction**

- |              |   |
|--------------|---|
| 2004-present | Medical Intensive Care Unit. Attending physician 4 to 6 weeks per year, Johns Hopkins.                        |
| 2004-present | Pulmonary Consultation Service. Attending physician four weeks per year, Johns Hopkins.                       |
| 2004-present | Lung Transplantation and Pulmonary Hypertension Service. Attending physician 8 weeks per year, Johns Hopkins. |
| 2004-present | Pulmonary Physiology Service. Attending physician four weeks per year, Johns Hopkins.                         |
| 2005-present | Janeway Firm Faculty. Teaching Attending 4 weeks per year, Johns Hopkins.                                     |

### **CME Instruction**

- |      |   |
|------|---|
| 5/06 | PFT interpretation, Topics/Tumulty Rounds, Johns Hopkins, Baltimore, MD.  |
| 4/06 | Challenging infections among adults with cystic fibrosis. Medical Grand Rounds. Johns Hopkins, Baltimore, MD                    |
| 8/07 | Update in Pulmonary and Critical Care Medicine, Johns Hopkins, Williamsburg VA.   |
| 1/07 | Cough for the Allergist, Allergy Symposium, Bayview Medical Center, Baltimore, MD.  |
| 7/08 | Update in Pulmonary and Critical Care Medicine, Johns Hopkins, Bar Harbor ME.   |
| 2/09 | Hereditary Hemorrhagic Telangiectasia- A Fresh Start to an Old Disease. Medical Grand Rounds. Johns Hopkins, Baltimore, MD.     |
| 7/09 | Update in Pulmonary and Critical Care Medicine, Johns Hopkins, Washington DC.   |
| 1/10 | An update in Cystic Fibrosis, Allergy Lecture Series, Johns Hopkins, Baltimore, MD.   |
| 4/12 | Nutritional Considerations after Lung Transplantation in Cystic Fibrosis. Nutrition Grand Rounds. Johns Hopkins, Baltimore, MD. |
| 9/12 | Hereditary Hemorrhagic Telangiectasia. Medical Grand Rounds. Johns Hopkins Bayview. Baltimore, MD.                              |
| 5/14 | A Curious Case of Hypoxemia, Topics/Tumulty Rounds, Johns Hopkins, Baltimore, MD.   |

9/14 Creating a Common Language in Cystic Fibrosis to Improve Adherence, Lecturer, Med-IQ. [www.med-iq.com/a796](http://www.med-iq.com/a796)

#### **Workshops/ Seminars**

5/08 Invited Lecturer, Observational Studies, Short Course in Epidemiology. American Thoracic Society, Toronto, ON.

10/09 Symposium Chairperson, Infectious Complications in Cystic Fibrosis. North American Cystic Fibrosis Conference, Minneapolis MN.

10/10 Symposium Chairperson, End Stage Lung Disease in CF: From Lung transplantation to Palliative Care, North American Cystic Fibrosis Conference, Baltimore, MD.

10/10 Invited Lecturer. Rise and Shine Workshop Management of Hemoptysis and Pneumothorax in Cystic Fibrosis. North American Cystic Fibrosis Conference, Baltimore, MD.

#### **Mentoring**

##### **Advisees**

2006-2010 Elliott Dasenbrook, MD MHS, Post-doctoral Fellow, Pulmonary and Critical Care Medicine Johns Hopkins University, currently Assistant Professor of Medicine at Case Western Reserve, Cleveland, OH.

2006-2010 Jeffrey Hoag, MD, Post-doctoral Fellow, Pulmonary and Critical Care Medicine, Johns Hopkins University, currently Assistant Professor of Medicine at Drexel University, Philadelphia, PA.

2008-2011 Brad Drummond, MD MHS, Post-doctoral Fellow, Pulmonary and Critical Care Medicine, Johns Hopkins University, currently Assistant Professor of Medicine, Johns Hopkins University, Baltimore MD.

2008-2012 Natalie West, MD MHS, Post-doctoral Fellow, Pulmonary and Critical Care Medicine, Johns Hopkins University, currently Assistant Professor of Medicine at Johns Hopkins University, Baltimore, MD.

2009-2011 Eric Weiss, MD MPH, Master's of Public Health student at Johns Hopkins Bloomberg School of Public Health, currently Assistant Professor of Surgery (adjunct) at Columbia College of Physicians and Surgeons, New York, NY.

2010-2012 Jeremiah Allen, MD, Resident, Johns Hopkins University, currently Attending Cardiac Surgeon, Kaiser Permanente, San Francisco, CA.

2010-present Andrew Braun, MD MHS, Post-doctoral Fellow, Pulmonary and Critical Care Medicine, Johns Hopkins University, currently Instructor of Medicine, Johns Hopkins University, Baltimore, MD.

2011-2013 Timothy George, MD, Resident, Johns Hopkins University, currently Resident Surgeon at Johns Hopkins University, Baltimore, MD.

2011-2014 Arman Kilic, MD, Resident, Johns Hopkins University, currently Resident Surgeon, Johns Hopkins University, Baltimore, MD.

2011-present Mark Jennings, MD, Post-doctoral Fellow, Pulmonary and Critical Care Medicine, Johns Hopkins University, currently Instructor of Medicine, Johns Hopkins University, Baltimore, MD.

2012-2016 Allison Lambert, MD MHS, Post-doctoral Fellow, Pulmonary and Critical Care Medicine, Johns Hopkins University, currently Instructor of Medicine, Johns Hopkins University, Baltimore, MD.

2012-2016 George Arnaoutakis, MD, Resident, Johns Hopkins University, currently Cardiac Surgery Fellow, University of Pennsylvania, Philadelphia, PA.

2014-present Joshua Grimm, MD, Resident, Johns Hopkins University, currently Resident Surgeon, Johns Hopkins University, Baltimore, MD.

2014-present Linda Yin, Medical student, Johns Hopkins University, currently a medical student at Johns Hopkins University, Baltimore, MD.

2015-present Todd Crawford, MD, Resident, Johns Hopkins University, currently Resident Surgeon, Johns Hopkins University, Baltimore, MD.

2015-present Trent Magruder, MD, Resident, Johns Hopkins University, currently Resident Surgeon, Johns Hopkins University, Baltimore, MD.

#### **Educational Program Building/ Leadership**

2006-present Course Director, Design of Clinical Studies, Johns Hopkins Bloomberg School of Public Health. This is an ongoing course available in the 2<sup>nd</sup> term each year through the Department of Epidemiology in the School of Public Health. It is part of a series of courses known formally together as the Science of

Clinical Investigation series. Together these courses convey the fundamentals of clinical research. In my capacity as director, I am responsible each year for the syllabus, lectures, homework assignments, and follow-up questions which arise during the 12-week class. The course has expanded over the years starting with a class size of about 6-8 to now over 40 per term and now includes physicians, nurses, administrators, and research coordinators.

2012-present Course Director, Distance Education Design of Clinical Studies, Johns Hopkins Bloomberg School of Public Health. This is a fully online version of the above course available through the Office of Distance Education in the 3<sup>rd</sup> term. Lectures, assignments, and quizzes are all available online. Live sessions accompany the online media. This course has also expanded from just a few to over 30 students per session.

#### **Educational Extramural Funding (Current, Pending, Previous) - None**

#### **CLINICAL ACTIVITIES**

##### **Certification**

##### Medical

1998	Medical License, Commonwealth of Virginia	0101057430	Inactive
1999	Medical License, District of Columbia	MD31720	Inactive
2004-present	Medical License, Maryland	D0061725	Active

##### Boards

2000	Diplomate, Internal Medicine, American Board of Internal Medicine
2003	Diplomate, Pulmonary Disease, American Board of Internal Medicine
2005	Diplomate, Critical Care Medicine, American Board of Internal Medicine

##### **Clinical Responsibilities**

2004-present	Medical Intensive Care Unit. Attending physician 4 to 6 weeks per year, JHH.
2004-present	Pulmonary Consultation Service. Attending physician four weeks per year, JHH.
2004-present	Lung Transplantation and Pulmonary Hypertension Service. Attending physician 8 weeks per year, JHH.
2004-present	Pulmonary Physiology Service. Attending physician four weeks per year, JHH.
2004-present	Attend in the Adult Cystic Fibrosis Clinic. One half day per week
2009-present	Attend in HHT Clinic. One half day per month
2011-present	Attend in the Lung Transplantation Clinic. One half day per week

##### **Clinical Program Building/Leadership**

2010-2018	Director, Johns Hopkins Hereditary Hemorrhagic Telangiectasia Center of Excellence. In my capacity, I am responsible for the coordination of multidisciplinary care for the patients with HHT that we care for at Johns Hopkins. Working in partnership with Sally Mitchell, MD, we created the Johns Hopkins HHT Center of Excellence in 2010, one of 17 such centers in the United States. The center now includes over 35 specialists from 15 Hopkins Departments and Divisions and has increased exponentially in size to include over 400 patients and family members. The team at Hopkins now consists of a nurse coordinator as well as specialists from nearly every division and department within the Hopkins system.
2015-present	Associate Program Director, Johns Hopkins Adult Cystic Fibrosis Center. In my capacity, I assist the Program and Center Director in the coordination of care guidelines and the delivery of clinical care in both the inpatient and outpatient settings, assist with coordination of clinical trials, and provide education to medical students, physicians, nurses, respiratory and physical therapists, nutritionists, social workers, patients, and family members regarding the multidisciplinary subspecialty care needed for patients with CF.

#### **Clinical Extramural Funding (Current, Pending, Previous) - None**

#### **SYSTEM INNOVATION AND QUALITY IMPROVEMENT ACTIVITIES - None**

## ORGANIZATIONAL ACTIVITIES

### Institutional Administrative Appointments

2003-2005 Educational Committee, Division of Pulmonary and Critical Care Medicine  
 2005-present Faculty Recruitment Committee, Division of Pulmonary and Critical Care  
 2014-present Assistant Director of Outpatient Services, Johns Hopkins Division of Pulmonary and Critical Care Medicine  
 2015-present Associate Program Director, Adult Cystic Fibrosis Center, Johns Hopkins Cystic Fibrosis Center

**Editorial Activities** - Not Applicable

### Journal Reviewer

2009-present Chest  
 2009-present Journal of Heart and Lung Transplant  
 2009-present Journal of Cystic Fibrosis  
 2009-present European Respiratory Journal  
 2009-present American Journal of Transplantation

### Advisory Committees, Review Groups/Study Sections

2012-present Member, Cystic Fibrosis Foundation Grant review Committee

### Professional Societies

2004-present Member, American Thoracic Society  
 2004-present Member, American College of Chest Physicians  
 2010-present Member, International Society for Heart and Lung Transplant

**Conference Organizer, Session Chair** - Not Applicable

**Consultantships** - Not Applicable

## RECOGNITION

### Awards, Honors

1999 Clinical Pearls Student Teaching Appreciation Award  
 1999 The William P. Argy Memorial House Staff Award  
 2000 Alpha Omega Alpha, Georgetown University  
 2003 DC Thoracic Society Annual Conference Award  
 2003 NIH Loan Repayment Program Award for Clinical Research  
 2005 Janeway Firm Faculty  
 2005 CHEST Foundation's Young Investigator Award  
 2005 NIH Loan Repayment Program Award for Clinical Research  
 2010 Fellows Teaching Award, Johns Hopkins

### Invited Talks

Local/National/International  
 2005 Speaker, Medical Grand Rounds. Virginia Hospital Center. "The Care of Adults with Cystic Fibrosis". Arlington, VA  
 2005 Speaker, Pulmonary Grand Rounds. The University of Pittsburgh. "The influence of environmental and genetic factors on outcomes in cystic fibrosis". Pittsburgh, PA.  
 2007 Plenary Speaker, International Society for Heart and Lung Transplant. "The effect of the Lung Allocation Score (LAS) on survival after lung transplantation". San Francisco, CA.  
 2008 Speaker, North American Cystic Fibrosis Conference. "The Impact of the LAS on Outcomes in CF". Orlando, FL.  
 2008 Speaker, Mid Atlantic Thoracic Society Conference. "Adult Cystic Fibrosis". Richmond, VA.  
 2009 Speaker, Hereditary Hemorrhagic Telangiectasia International Scientific Conference. "Quality of Life among Patients with Hereditary Hemorrhagic Telangiectasia". Santander, Spain.  
 2010 Speaker/ Session Chair, Society for General Internal Medicine. "Research During Residency- Striking the Balance at Hopkins". Minneapolis, MN.

- 2010 Speaker/ Session Chair, North American Cystic Fibrosis Conference. "Lung Transplantation and Cystic Fibrosis". Baltimore, MD.
- 2010 Speaker, Pulmonary Grand Rounds. Brown University. "Hereditary Hemorrhagic Telangiectasia". Providence, RI.
- 2010 Speaker, 8<sup>th</sup> International Congress on Lung Transplantation. "Understanding and Dissecting the Lung Allocation Scoring System". Paris, France.
- 2012 Speaker, Medical Grand Rounds. Georgetown University Hospital. "Adult Cystic Fibrosis". Washington, DC.
- 2012 Speaker, 16<sup>th</sup> Annual HHT Patient and Family Day, HHT Foundation, "Understanding Screening for HHT." Orlando, FL.
- 2013 Speaker, American Thoracic Society. "Understanding and Dissecting the Lung Allocation Scoring System". Philadelphia, PA.
- 2013 Speaker, Cystic Fibrosis Conference Mexico. "Outcomes in Adults with Cystic Fibrosis". Mexico City, Mexico.
- 2013 Speaker, Hereditary Hemorrhagic Telangiectasia International Scientific Conference. "Minimal Clinical Important Difference in Epistaxis Severity Score in HHT". Cork, Ireland.
- 2014 Speaker, Medical Grand Rounds. Virginia Hospital Center. "Adult Cystic Fibrosis". Arlington, VA.

#### **OTHER PROFESSIONAL ACCOMPLISHMENTS**

- 2013 Washington Post. When should you start worrying about that lingering cough? Give it time. [http://www.washingtonpost.com/national/health-science/when-should-you-start-worrying-about-that-lingering-cough-give-it-time/2013/12/20/1e615e9c-665d-11e3-ae56-22de072140a2\\_story.html](http://www.washingtonpost.com/national/health-science/when-should-you-start-worrying-about-that-lingering-cough-give-it-time/2013/12/20/1e615e9c-665d-11e3-ae56-22de072140a2_story.html)
- 2013 Hopkins Medicine. For Lung Transplant, Researchers Surprised to Learn Bigger Appears to Be Better. [http://www.hopkinsmedicine.org/news/media/releases/for\\_lung\\_transplant\\_researchers\\_surprised\\_to\\_learn\\_bigger\\_appears\\_to\\_be\\_better\\_](http://www.hopkinsmedicine.org/news/media/releases/for_lung_transplant_researchers_surprised_to_learn_bigger_appears_to_be_better_)
- 2014 Cover photograph entitled "A View of the Dome". Annals of the American Thoracic Society, Volume 11, Issue 5. <http://www.atsjournals.org/toc/annalsats/11/5>
- 2014 Johns Hopkins Health. Calming that cough. [http://www.hopkinsmedicine.org/news/publications/johns\\_hopkins\\_health/fall\\_2014/calming\\_that\\_cough](http://www.hopkinsmedicine.org/news/publications/johns_hopkins_health/fall_2014/calming_that_cough)
- 2015 EurekAlert! Lung transplant patients in the UK fare better than publicly insured Americans. [http://www.eurekalert.org/pub\\_releases/2015-03/jhm-ltp031915.php](http://www.eurekalert.org/pub_releases/2015-03/jhm-ltp031915.php)



# APPENDIX B

## **APPENDIX B**

### List of Literature Review and Materials Considered by Dr. Christian Merlo

1. Abenhaim et al., *Appetite-Suppressant Drugs and the Risk of Primary Pulmonary Hypertension*. (1996) 335(9) N Engl J Med 609
2. Berge et al., *Genital use of talc and risk of ovarian cancer: a meta-analysis*. (2018) 27 Eur J Cancer Prev 248
3. Booth et al., *Risk factors for ovarian cancer: a case-control study*. (1989) 60(4) Br J Cancer. 592
4. Centers for Disease Control & Prevention, *Principles of Epidemiology in Public Health Practice, Third Edition, An Introduction to Applied Epidemiology and Biostatistics, Lesson 1: Introduction to Epidemiology*,  
<https://www.cdc.gov/ophss/csels/dsepd/ss1978/lesson1/section1.html>
5. Chang & Risch., *Perineal talc exposure and risk of ovarian carcinoma*. (1997) 79(12) Cancer. 2396
6. Chen et al., *Risk factors for epithelial ovarian cancer in Beijing, China*. (1992) 21(1) Int J Epidemiol. 23
7. Cook et al., *Perineal powder exposure and the risk of ovarian cancer*. (1997) 145(5) Am J Epidemiol. 459
8. Cramer & Xu, *Epidemiologic evidence for uterine growth factors in the pathogenesis of ovarian cancer*. (1995) 5 Ann Epidemiol. 310
9. Cramer et al., *Ovarian cancer and talc: a case-control study*. (1982) 50(2) Cancer 372
10. Cramer et al., *The Association Between Talc Use and Ovarian Cancer: A Retrospective Case-Control Study in Two US States*. (2016) 27(3) Epidemiology 334
11. Cramer et al., *Genital talc exposure and risk of ovarian cancer*. (1999) 81(3) Int J Cancer. 351
12. Deposition of Anne McTiernan, M.D., Ph.D., Jan. 28, 2019 (MDL No. 2738)
13. Deposition of April Zambelli-Weiner, Ph.D., Jan. 11, 2019 (MDL No. 2738)
14. Deposition of April Zambelli-Weiner, Ph.D., Feb. 7, 2019 (MDL No. 2738)
15. Deposition of Ghassan Saed, Ph.D., Jan. 23, 2019 (MDL No. 2738)
16. Deposition of Ghassan Saed, Ph.D., Feb. 14, 2019 (MDL No. 2738)
17. Deposition of Jack Siemiatycki, Jan. 31, 2019 (MDL No. 2738)
18. Deposition of Rebecca Smith-Bindman, M.D., Feb. 7, 2019 (MDL No. 2738)
19. Deposition of Rebecca Smith-Bindman, M.D., Feb. 8, 2019 (MDL No. 2738)
20. Deposition of Patricia Moorman, M.S.P.H., Ph.D., Jan. 25, 2019 (MDL No. 2738)
21. Deposition of Sonal Singh, M.D., M.P.H., Jan. 16, 2019 (MDL No. 2738)
22. Doll & Hill, *The mortality of doctors in relation to their smoking habits*. (1954) 328 (7455) BMJ 1529
23. Expert Report of Anne McTiernan, M.D., Ph.D., Nov. 16, 2018 (MDL No. 2738)
24. Expert Report of April Zambelli-Weiner, Ph.D., M.P.H., Nov. 16, 2018 (MDL No. 2738)
25. Expert Report of Ghassan Saed, Ph.D., Nov. 16, 2018 (MDL No. 2738)
26. Expert Report of Jack Siemiatycki, M.Sc., Ph.D., Nov. 16, 2018 (MDL No. 2738)
27. Expert Report of Patricia Moorman, M.S.P.H., Ph.D., Nov. 16, 2018 (MDL No. 2738)
28. Expert Report of Rebecca Smith-Bindman, M.D., Nov. 15, 2019 (MDL No. 2738)
29. Expert Report of Sonal Singh, M.D., M.P.H., Nov. 16, 2018 (MDL No. 2738)

30. Gates et al., *Risk Factors for Epithelial Ovarian Cancer by Histologic Subtype*. (2010) 171 Am. J. Epidemiology 45
31. Gates et al., *Talc use, variants of the GSTM1, GSTT1, and NAT2 genes, and risk of epithelial ovarian cancer*. (2008) 17(9) Cancer Epidemiol Biomarkers 2436
32. Gertig et al., *Prospective Study of Talc Use and Ovarian Cancer*. (2000) 92 J. Nat. Cancer Inst. 249
33. Godard et al., *Risk factors for familial and sporadic ovarian cancer among French Canadians: a case-control study*. (1998) 179(2) Am J Obstet Gynecol. 403
34. Gonzalez et al., *Douching, Talc Use, and Risk of Ovarian Cancer*. (2016) 27 Epidemiology 797
35. Green A, Purdie D, Bain C, et al., *Tubal sterilisation, hysterectomy and decreased risk of ovarian cancer. Survey of Women's Health Study Group*. (1997) 71(6) Int J Cancer. 948
36. Grimes & Schultz, *Bias and causal associations in observational research*. (2002) 259(9302) Lancet 248
37. Gross & Berg, *A meta-analytical approach examining the potential relationship between talc exposure and ovarian cancer*. (1995) 5(2) J Expo Anal Environ Epidemiol. 181
38. Harlow & Weiss, *A case-control study of borderline ovarian tumors: the influence of perineal exposure to talc*. (1989) 130(2) Am J Epidemiol. 390
39. Harlow et al., *Perineal exposure to talc and ovarian cancer risk*. (1992) 80(1) Obstet Gynecol. 19
40. Hartge & Stewart., *Occupation and ovarian cancer: a case-control study in the Washington, DC, metropolitan area, 1978-1981*. (1994) 36(8) J Occup Med. 924
41. Hartge et al., *Talc and Ovarian Cancer*, (1983) 250 J. Am. Med. Ass'n 1844
42. Hill, *Environment and disease: association or causation?* (1965) 58 Proc Royal Soc Med. 295
43. Houghton et al., *Perineal Powder Use and Risk of Ovarian Cancer*. (2014) 106(9) J Nat. Cancer Inst
44. Huncharek et al., *Perineal Application of Cosmetic Talc and Risk of Invasive Epithelial Ovarian Cancer: A Meta-analysis of 11,933 Subjects from Sixteen Observational Studies*. (2003) 23 Anticancer Res. 1955
45. Huncharek et al., *Use of cosmetic talc on contraceptive diaphragms and risk of ovarian cancer: a meta-analysis of nine observational studies*. (2007) 18 Eur J Cancer Prev 422
46. Infante-Rivard, *Hospital or Population Controls for Case-Control Studies of Sever Childhood Diseases?* (2003) 157(2) Am J Epidemiol 176
47. Jordan et al., *Risk factors for benign, borderline and invasive mucinous ovarian tumors: Epidemiological evidence of a neoplastic continuum?* (2007) 107 Gynecol. Oncol. 223
48. Jordan et al., *Risk factors for benign serous and mucinous epithelial ovarian tumors*. (2007) 109(3) Obstet Gynecol. 647
49. Kurta et al., *Use of Fertility Drugs and Risk of Ovarian Cancer: Results from a U.S.-Based Case-Control Study*. (2012) 21(8) Cancer Epidemiol Biomarkers Prev. 1282
50. Langseth et al., *Perineal use of talc and risk of ovarian cancer*. (2008) 62 J Epidemiol Community Health 358
51. Malmberg et al., *Serous tubal intraepithelial carcinoma, chronic fallopian tube injury, and serous carcinoma development*. (2016) 468(6) Virchows Arch. 707-13
52. Merritt et al., *Talcum Powder, chronic pelvic inflammation and NSAIDs in relation to risk of epithelial ovarian cancer*. (2008) 122 Int'l J. Cancer 170

53. Mills et al., *Perineal Talc Exposure and Epithelial Ovarian Cancer Risk in the Central Valley of California*. (2004) 112 Int'l J. Cancer 458
54. Moorman et al., *Ovarian Cancer Risk Factors in African-American and White Women*. (2009) 170(5) Am J Epidemiol 598
55. Narod, *Talc and ovarian cancer*. (2016) 141 Gynecol. Oncol. 410
56. Nat. Cancer Inst., *Cancer Stat Facts: Ovarian Cancer*, <https://seer.cancer.gov/statfacts/html/ovary.html>
57. Nat. Cancer Inst., *Ovarian, Fallopian Tube, and Primary Peritoneal Cancer Prevention (PDQ) – Health Professional Version*, [https://www.cancer.gov/types/ovarian/hp/ovarian-prevention-pdq#link/\\_220\\_toc](https://www.cancer.gov/types/ovarian/hp/ovarian-prevention-pdq#link/_220_toc) (last updated Jan. 4, 2019)
58. Nat. Health & Medical Res. Council, *NHMRC Levels of Evidence and Grades for Recommendations for Developers of Clinical Practice Guidelines* (2009)
59. Ness et al., *Factors related to inflammation of the ovarian epithelium and risk of ovarian cancer*. (2000) 11(2) Epidemiology 111
60. Oleckno, *Epidemiology: Concepts and Methods*. (2008)
61. Penninkilampi and Eslick, *Perineal Talc Use and Ovarian Cancer: A Systematic Review and Meta-Analysis*. (2018) 29(1) Epidemiology 41
62. Pike et al., *Hormonal factors and the risk of invasive ovarian cancer: a population-based case-control study*. (2004) 82(1) Fertil Steril. 186
63. Purdie et al., *Reproductive and other factors and risk of epithelial ovarian cancer: an Australian case-control study*. Survey of Women's Health Study Group. (1995) 62(6) Int J Cancer. 678
64. Rosenblatt et al., *Genital powder exposure and the risk of epithelial ovarian cancer*. (2011) 22 Cancer Causes Control 737
65. Rosenblatt et al., *Mineral Fiber Exposure and the Development of Ovarian Cancer*, (1992) 45 Gynecologic Oncology 20
66. Rosenblatt et al., *Characteristics of women who use perineal powders*. (1998) 92(5) Obstet Gynecol 753
67. Schildkraut et al., *Association between Body Powder Use and Ovarian Cancer: The African American Cancer Epidemiology Study (AACES)*. (2016) 25(10) Cancer Epidemiol Biomarkers Prev. 1411
68. Schlesselman, *Case-control studies: design, conduct, analysis* (1982)
69. Schultz & Grimes, *Case-control studies: research in reverse*. (2002) 359(9304) Lancet 431
70. Shushan et al., *Human menopausal gonadotropin and the risk of epithelial ovarian cancer\**. (1996) 65(1) Fertil Steril. 13
71. Terry et al., *Genital Powder Use and Risk of Ovarian Cancer: A Pooled Analysis of 8,525 Cases and 9,859 Controls*. (2013) 6(8) Cancer Prev Res 811
72. The Scandinavian Simvastatin Survival Study Group. *Design and baseline results of the Scandinavian Simvastatin Survival Study of patients with stable angina and/or previous myocardial infarction*. (1993) 71 Am J Cardiol 393
73. Tzonou et al., *Hair dyes, analgesics, tranquilizers and perineal talc application as risk factors for ovarian cancer*. (1993) 55(3) Int J Cancer. 408
74. Vavken & Dorotka, *A Systematic Review of Conflicting Meta-Analyses in Orthopaedic Surgery*. (2009) 467(10) Clin Orthop Relat Res. 2723

75. Vetter & Mascha, *Bias, Confounding, and Interaction: Lions and Tigers, and Bears, Oh My!*, (2017) 125(3) *Anesth Analg* 1042
76. Wang et al., *Statistics in Medicine – Reporting of Subgroup Analyses in Clinical Trials*. (2007) 357(21) *N Engl J Med* 2189
77. Whittemore et. al., *Personal And Environmental Characteristics Related To Epithelial Ovarian Cancer*, (1988) 128 *Am J. Epidemiol* 1228
78. Wong et al. *Perineal talc exposure and subsequent epithelial ovarian cancer: a case-control study*. (1999) 93 *Obstet Gynecol* 372
79. Wu et al., *African Americans and Hispanics Remain at Lower Risk of Ovarian Cancer Than Non-Hispanic Whites after Considering Nongenetic Risk Factors and Oophorectomy Rates*. (2015) 24(7) *Cancer Epidemiol Biomarkers Prev.* 1094
80. Wu et al., *Markers of inflammation and risk of ovarian cancer in Los Angeles County*. (2009) 124 *Int'l J. Cancer* 1409
81. Wynder et al., *Radford Conference Report: Weak associations in epidemiology and their interpretation (3rd ed.)*. (1982) 11 *Prev. Med*

# APPENDIX C



**Fed. R. Civ. P. 26(a)(2)(B)(v) Disclosure for Christian Merlo, M.D., M.P.H.**

Year	Parties	State	Caption
2015	Blevins v. Pyron	Missouri	Blevins v. Pyron Lawrence County Circuit Court 14LW-CC00108
2015	Grove v. UMMS	Maryland	Grove v. UMMS USDC Maryland 12-cv-2950
2015	Dutton v. UMMS	Maryland	Dutton v. UMMS Baltimore City Circuit Court 24-C-14-003848
2015	Hawkins v. Mercy Kansas	Missouri	Hawkins v. Mercy Kansas St. Louis City Circuit Court 1422-CC09810
2015	Whitehead v. CVS	Florida	Whitehead v. CVS Miami-Dade County Circuit Court 14-25980CA01
2016	Evans v. Livingston Health Care	Montana	Evans v. Livingston Health Care Gallatin County District Court DV-11-990B
2016	Moore v. Mercy	Maryland	Moore v. Mercy Baltimore City Circuit Court 24-C-16-004483
2016	Quintanilla v. Narayanan	Maryland	Quintanilla v. Narayanan Montgomery County Circuit Court 397252V
2017	Burns v. Bowser	Virginia	Burns v. Bowser Virginia 13th Judicial Circuit CL14005484-00
2017	Monroe v. Franklin Square	Maryland	Monroe v. Franklin Square Baltimore County Circuit Court 03-C-16-001886
2017	Weisman v. Maryland General	Maryland	Weisman v. Maryland General Baltimore City Circuit Court 24-C-16-004199
2017	Almquist v. Kinsey	Maryland	Almquist v. Kinsey USDC Maryland 1:15cv292
2017	Sullivan v. Holy Cross	Maryland	Sullivan v. Holy Cross Montgomery County Circuit Court 423516v
2018	Flores v. Kaiser	Maryland	Flores v. Kaiser Montgomery County Circuit Court 427661v
2018	Hamlin-Lewis v. Guckes	Maryland	Hamlin-Lewis v. Guckes USDC Maryland 1:16cv3357
2018	Hirschenson v. Cleveland Clinic	Florida	Hirschenson v. Cleveland Clinic Broward County Circuit Court CACE13001180
2018	Knoerlein v. Express Primary Care	Maryland	Knoerlein v. Express Primary Care Baltimore County Circuit Court 03-C-17-001137
2018	McRae v. Dimensions Health	Maryland	McRae v. Dimensions Health Prince George's County Circuit Court CAL1702184
2018	Fluoroquinolone Liability Litigation	New Jersey	
2019	Jones v. Agrawal	Maryland	Jones vs Bon Secours Hospital Baltimore, Inc, et al ("Jones v. Agrawal") Baltimore County Circuit Court 24C18000398

# Exhibit 7

Christian Merlo, M.D., MPH

Page 1

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & )  
JOHNSON TALCUM POWDER )  
PRODUCTS MARKETING )  
SALES PRACTICES AND ) MDL 16-2738  
PRODUCT LIABILITY ) (FLW)(LHG)  
LITIGATION )  
\_\_\_\_\_)  
THIS DOCUMENT )  
PERTAINS TO ALL CASES )

THURSDAY, APRIL 18, 2019

- - -

Videotaped deposition of Christian  
Merlo, M.D., MPH, held at the offices of  
VENABLE LLP, 750 East Pratt Street, Suite  
900, Baltimore, Maryland, commencing at 9:06  
a.m., on the above date, before Carrie A.  
Campbell, Registered Diplomate Reporter  
and Certified Realtime Reporter.

- - -

GOLKOW LITIGATION SERVICES  
877.370.3377 ph | 917.591.5672 fax  
deps@golkow.com

Christian Merlo, M.D., MPH

Page 2	Page 4
<p>1 APPEARANCES:</p> <p>2 LEVIN, PAPANTONIO, THOMAS, MITCHELL,</p> <p>3 RAFFERTY &amp; PROCTOR, P.A.</p> <p>4 BY: CHRISTOPHER V. TISI</p> <p>5 ctisi@levinlaw.com</p> <p>6 316 South Baylen Street, Suite 600</p> <p>7 Pensacola, Florida 32502</p> <p>8 (850) 435-7000</p> <p>9</p> <p>10 RESTAINO LAW LLC</p> <p>11 BY: JOHN M. RESTAINO, JR., DPM, JD, MPH</p> <p>12 JRestaino@RestainoLLC.com</p> <p>13 130 Forest Street</p> <p>14 Denver, Colorado 80220</p> <p>15 (303) 839-8000</p> <p>16</p> <p>17 ASHCRAFT &amp; GEREL, LLP</p> <p>18 BY: MICHELLE A. PARFITT</p> <p>19 mparfitt@ashcraftlaw.com</p> <p>20 4900 Seminary Road, Suite 650</p> <p>21 Alexandria, Virginia 22311</p> <p>22 (703) 931-5500</p> <p>23</p> <p>24 ROBINSON CALCAGNIE, INC.</p> <p>25 BY: CYNTHIA L. GARBER</p> <p>cgarber@robinsonfirm.com</p> <p>19 Corporate Plaza Drive</p> <p>Newport Beach, California 92660</p> <p>(949) 720-1288</p> <p>WAGNER REESE LLP</p> <p>BY: JEFF S. GIBSON</p> <p>JGibson@WagnerReese.com</p> <p>11939 North Meridian Street</p> <p>Carmel, Indiana 46032</p> <p>Counsel for Plaintiffs</p>	<p>1 VIDEOGRAPHER:</p> <p>2 DANIEL HOLMSTOCK, Golkow Litigation</p> <p>3 Services</p> <p>4 ---</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
Page 3	Page 5
<p>1 DRINKER BIDDLE &amp; REATH LLP</p> <p>2 BY: SUSAN M. SHARKO</p> <p>3 Susan.Sharko@db.com</p> <p>4 600 Campus Drive</p> <p>5 Florham Park, New Jersey 07932-1047</p> <p>6 (973) 549-7000</p> <p>7</p> <p>8 DRINKER BIDDLE &amp; REATH LLP</p> <p>9 BY: KATHERINE MCBETH</p> <p>10 katherine.mcbeth@db.com</p> <p>11 One Logan Square, Suite 2000</p> <p>12 Philadelphia, Pennsylvania 19103</p> <p>13 (215) 988-2700</p> <p>14 and</p> <p>15</p> <p>16 SKADDEN ARPS SLATE MEAGHER &amp; FLOM LLP</p> <p>17 BY: JESSICA D. MILLER</p> <p>18 jessica.miller@skadden.com</p> <p>19 1440 New York Avenue N.W.</p> <p>20 Washington, DC 20005</p> <p>21 (202) 371-7000</p> <p>22 Counsel for Defendant Johnson &amp;</p> <p>23 Johnson</p> <p>24</p> <p>25 SEYFARTH SHAW LLP</p> <p>BY: THOMAS T. LOCKE</p> <p>tlocke@seyfarth.com</p> <p>975 F Street, N.W.</p> <p>Washington, DC 20004</p> <p>(202) 463-2400</p> <p>Counsel for Defendant Personal Care</p> <p>Products Council</p> <p>TUCKER ELLIS, LLP</p> <p>BY: MICHAEL ANDERTON</p> <p>michael.anderton@tuckerellis.com</p> <p>950 Main Avenue, Suite 1100</p> <p>Cleveland, Ohio 44113</p> <p>(216) 592-5000</p> <p>Counsel for PTI Union, LLC and PTI</p> <p>Royston, LLC</p>	<p>1 INDEX</p> <p>2 PAGE</p> <p>3 APPEARANCES..... 2</p> <p>4 EXAMINATIONS</p> <p>5 BY MR. TISI..... 11</p> <p>6 BY MS. MILLER..... 479</p> <p>7 BY MR. TISI..... 483</p> <p>8</p> <p>9 EXHIBITS</p> <p>10 No. Description Page</p> <p>11 Merlo 1 Curriculum Vitae of Christian A. 11</p> <p>Merlo, MD, MPH</p> <p>12</p> <p>13 Merlo 2 Pulmonary &amp; Critical Care 13</p> <p>Medicine printout</p> <p>14 Merlo 3 Expert Report of Christian 32</p> <p>Merlo, MD, MPH, for General</p> <p>15 Causation Daubert Hearing</p> <p>16 Merlo 3A Expert Report of Christian 33</p> <p>Merlo, MD, MPH, Supplemental</p> <p>17 Materials Reviewed and</p> <p>Considered</p> <p>18</p> <p>19 Merlo 3B March 13, 2019 letter from Susan 78</p> <p>Sharko to Michelle Parfitt</p> <p>20 Merlo 4 Christian Merlo, MD, MPH 54</p> <p>biography printout from Johns</p> <p>21 Hopkins website</p> <p>22 Merlo 5 Johns Hopkins web page printout 57</p> <p>of Christian Merlo, MD, MPH,</p> <p>23 Adult Clinic for the Cystic</p> <p>Fibrosis Center</p> <p>24</p> <p>25</p>

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<p style="text-align: right;">Page 10</p> <p>1 VIDEOGRAPHER: We are now on 2 the record. 3 My name is Daniel Holmstock. 4 I'm the videographer for Golkow 5 Litigation Services. 6 Today's date is April 18, 2019, 7 and the time on the video screen is 8 9:06 a.m. 9 This deposition is being held 10 at the law offices of Venable LLP, 750 11 East Pratt Street, Suite 900, 12 Baltimore, Maryland, for the matter of 13 In Re: Johnson &amp; Johnson Talcum Powder 14 Products Marketing, Sales Practices 15 and Products Liability Litigation, MDL 16 Number 2738, pending before the United 17 States District Court for the Eastern 18 District of New Jersey. 19 Our deponent today is 20 Dr. Christian Merlo. 21 Counsel for the record will be 22 noted on the stenographic record for 23 appearances. 24 Our court reporter is Carrie 25 Campbell, who will now administer the</p>	<p style="text-align: right;">Page 12</p> <p>1 this year that would make it more current? 2 A. There are probably a couple of 3 articles that I need to put in there. 4 Q. Do any of them deal with 5 ovarian cancer? 6 A. They do not. 7 Q. Do any of them deal with talc? 8 A. They do not. 9 Q. Okay. Get back to your CV in a 10 moment. 11 You're a medical doctor? 12 A. I am. 13 Q. And you're board certified in 14 internal medicine? 15 A. Internal medicine, pulmonary 16 medicine and critical care medicine. 17 Q. Okay. And you are also an 18 associate professor of medicine in the 19 Department of Pulmonary and Critical Care 20 Medicine at Johns Hopkins University? 21 A. In the department of medicine 22 and also in the department of epidemiology at 23 the School of Public Health. 24 Q. I'll ask you about the second 25 later, but my specific question is that you</p>
<p style="text-align: right;">Page 11</p> <p>1 oath to the witness. 2 3 CHRISTIAN MERLO, M.D., MPH, 4 of lawful age, having been first duly sworn 5 to tell the truth, the whole truth and 6 nothing but the truth, deposes and says on 7 behalf of the Plaintiffs, as follows: 8 9 (Merlo Exhibit 1 marked for 10 identification.) 11 12 DIRECT EXAMINATION 13 QUESTIONS BY MR. TISI: 14 Q. Please state your name. 15 A. My name is Christian Merlo. 16 Q. And I've placed before you, 17 Dr. Merlo, a copy of your CV as Exhibit 1. 18 Do you see that? 19 A. I do. 20 Q. Is this your current CV? 21 This was produced to us in 22 connection with this litigation. 23 A. Seems about right. 24 Q. Okay. Is there anything that 25 needs to be added to it since February of</p>	<p style="text-align: right;">Page 13</p> <p>1 are associate professor of medicine in the 2 Department of Pulmonary and Critical Care 3 Medicine at Johns Hopkins University? 4 A. But my official title is an 5 associate professor of medicine in 6 epidemiology. 7 (Merlo Exhibit 2 marked for 8 identification.) 9 QUESTIONS BY MR. TISI: 10 Q. Okay. I would like you show 11 you what I would like to have marked as 12 Exhibit Number 2. 13 This is the -- 14 MR. TISI: I'm sorry, did you 15 put an exhibit sticker on it? 16 QUESTIONS BY MR. TISI: 17 Q. This is the web page to the 18 Johns Hopkins Division of Pulmonary and 19 Critical Care Medicine. 20 Do you see that? 21 A. I see the exhibit, yes. 22 Q. Okay. And who is Nadia Hansel? 23 A. Nadia Hansel is our current 24 division director of the pulmonary and 25 critical care division.</p>

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<p style="text-align: right;">Page 14</p> <p>1 Q. She basically runs your 2 division? 3 A. Well, she's part of the crew 4 that runs the division, but she's our 5 division director. 6 Q. Okay. And did you see where it 7 describes -- on the second paragraph it 8 describes the scope of conditions treated in 9 the department, Division of Pulmonary and 10 Critical Care Medicine? 11 A. I see that paragraph, yes. 12 Q. Let me read it for the record. 13 It says, "We hold clinical and 14 research expertise in a broad range of 15 diseases, including asthma, COPD, critical 16 care, cystic fibrosis, interstitial lung 17 disease, lung cancer, lung transplantation, 18 neuromuscular disease, pulmonary 19 hypertension, sarcoidosis and sleep 20 medicine." 21 Do you see that? 22 A. I do. 23 Q. Does the Johns Hopkins Division 24 of Pulmonary and Critical Care Medicine 25 provide primary care treatment for</p>	<p style="text-align: right;">Page 16</p> <p>1 care of patients like that. 2 Q. Okay. So -- I'm sorry. I 3 didn't mean to interrupt you. 4 So other than treating the side 5 effects that perhaps might occur in the 6 context of a patient who has gynecologic 7 cancers, people with ovarian cancer typically 8 are treated by oncologists; is that true? 9 Primarily? 10 A. Again, if we're talking about 11 oncologic therapy, yes, they would be 12 traditionally treated by oncologists. 13 Q. You're what's called an 14 associate professor? 15 A. I am an associate professor. 16 Q. Okay. And just to follow up on 17 the last question, you're not board certified 18 in oncology, are you? 19 A. I'm not. 20 Q. Do you have tenure? 21 A. Tenure is a tricky thing at 22 Hopkins. There's not really a full 23 definition of it. 24 The usual definition is if 25 you're asked to stay after an instructor, the</p>
<p style="text-align: right;">Page 15</p> <p>1 gynecologic cancers? 2 A. I think you'd have to define 3 primary care treatment. 4 Q. Yes. 5 A. We do have an oncologic center 6 where we take care of many patients who are 7 very, very sick with cancers, and some of 8 those involve gynecologic cancers, and we are 9 the primary caregiver in our onc ICU. 10 Q. Okay. But is that in the 11 Division of Pulmonary and Critical Care -- 12 A. Yes. 13 Q. -- Medicine? 14 Okay. But the treatment of 15 people who actually are diagnosed, until the 16 very end of their treatment, is not in your 17 division; is that correct? 18 A. Again, I think you'd have to 19 define what the treatment is -- 20 Q. Okay. 21 A. -- because sometimes the 22 treatment involved in gynecologic cancers 23 involves therapies that give side effects, 24 and those side effects land those patients in 25 some intensive care units where we do take</p>	<p style="text-align: right;">Page 17</p> <p>1 institution is committed to keeping you here. 2 Q. Okay. 3 A. But there's no contract that 4 one signs or that one gets saying "you can 5 stay here forever." 6 Q. You're not a full professor? 7 A. I am not a full professor. 8 Q. And your expertise is critical 9 care -- is in the care -- critical care -- 10 I'm sorry. 11 Your expertise has been 12 described as in critical care and cystic 13 fibrosis, and those with lung transplants as 14 well as patients who have other lung 15 diseases, as well as those who require 16 critical care therapy. 17 Is that true? 18 MS. MILLER: Objection. 19 Are you looking at this? 20 MR. TISI: I'm not -- you can 21 object. 22 THE WITNESS: No, you'd have to 23 show me where you're getting that. I 24 mean, I have lots of expertise. I 25 have expertise in internal medicine</p>

5 (Pages 14 to 17)

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<p style="text-align: right;">Page 18</p> <p>1 and a broad range of pulmonary 2 medicine, a broad range of critical 3 care medicine as well as lung 4 transplantation. 5 So I'm not sure where you got 6 that from, but if you show me 7 something I can -- 8 QUESTIONS BY MR. TISI: 9 Q. We'll do that. 10 I think you mentioned you don't 11 hold yourself out as an expert in oncology, 12 correct? 13 MS. MILLER: Objection. 14 THE WITNESS: I think what I 15 said before is I do have a broad range 16 of experience in taking care of 17 oncologic patients in our oncology 18 ICU, so I do consider myself an expert 19 in the intensive care unit care for 20 patients with oncologic disease. 21 QUESTIONS BY MR. TISI: 22 Q. Okay. Different question, 23 however. 24 Do you hold yourself out to 25 your colleagues as an expert -- as a cancer</p>	<p style="text-align: right;">Page 20</p> <p>1 Do you see that? 2 A. I do. 3 Q. And you identify, if I'm 4 reading correctly, 79 peer-reviewed papers? 5 A. Seems about right. 6 Q. Do any of your peer-reviewed 7 papers deal with gynecologic cancers? 8 A. There's one paper where we look 9 at the risk of malignancy after lung 10 transplantation, and I believe we looked at 11 certain -- I have to go back and look at the 12 paper, but I believe we looked at all sorts 13 of cancers, and gynecologic cancers may have 14 been in there as well. 15 Q. But the focus of the paper was 16 the consequences of lung transplantation, 17 correct? 18 A. The risk of malignancy after 19 lung transplantation. 20 Q. Do any of them deal 21 specifically with ovarian cancer and its 22 causes? 23 A. No. 24 Q. Do any of them deal with talcum 25 powder products?</p>
<p style="text-align: right;">Page 19</p> <p>1 expert? 2 MS. MILLER: Objection. 3 THE WITNESS: I'm going to have 4 to say the same thing, because part of 5 cancer does deal with patients who get 6 very, very, very sick. And as a 7 group, we have several in our group 8 who attend in our oncology ICU, and 9 I'm one of them, and I do have 10 specific expertise in that aspect of 11 oncology. 12 QUESTIONS BY MR. TISI: 13 Q. And you are not board certified 14 in oncology, however? 15 A. I believe I said I wasn't. 16 Q. And you're not a gynecologist? 17 A. I'm not a gynecologist. 18 Q. You're not a toxicologist? 19 A. I am not a toxicologist. 20 Q. You're not a mineralogist? 21 A. I'm not a mineralogist. 22 Q. Turning back to your CV, 23 Exhibit 1, page 2, you have a section 24 entitled "Peer Review, Original Science 25 Publications."</p>	<p style="text-align: right;">Page 21</p> <p>1 A. Excuse me. No. 2 Q. Do any of them deal with 3 asbestos? 4 A. No. 5 Q. In fact, you understand in this 6 case that there is a claim that there is 7 asbestos contamination or asbestos included 8 in talcum powder products, correct? 9 MS. MILLER: Objection. 10 THE WITNESS: I wasn't asked to 11 give an opinion on asbestos in this 12 case. 13 QUESTIONS BY MR. TISI: 14 Q. Okay. And I understand that, 15 and that was going to be my question. So I'm 16 going to ask you that you -- so we don't run 17 into problems here, I'm going to ask that you 18 listen to my question. Okay? 19 Do you understand that there is 20 an allegation in this case -- and if you 21 don't have an understanding, that's fine -- 22 that there is asbestos in talc -- Johnson &amp; 23 Johnson's talcum powder products? 24 MS. MILLER: Objection. 25 MR. LOCKE: Objection.</p>

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<p style="text-align: right;">Page 22</p> <p>1 THE WITNESS: Again, I wasn't</p> <p>2 asked to give an opinion about</p> <p>3 asbestos.</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. I didn't ask whether you were</p> <p>6 asked to give opinions.</p> <p>7 Do you have any understanding</p> <p>8 if that's part of the record in this case?</p> <p>9 MS. MILLER: Same objections.</p> <p>10 MR. LOCKE: Objection.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Okay. That's fine.</p> <p>13 So again, I'm going to ask you</p> <p>14 to listen to my question.</p> <p>15 So you're not offering an</p> <p>16 opinion as to whether or not talc -- the</p> <p>17 presence or -- the presence of asbestos</p> <p>18 provides a biologically plausible mechanism</p> <p>19 for talcum powder product causing ovarian</p> <p>20 cancer?</p> <p>21 A. So I have not reviewed the</p> <p>22 literature specifically about asbestos. I</p> <p>23 was not asked to provide an opinion about</p> <p>24 asbestos.</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 24</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. Yes.</p> <p>3 Were you asked to provide an</p> <p>4 opinion as to whether or not the presence of</p> <p>5 asbestos in talcum powder products is a</p> <p>6 biologically plausible mechanism for causing</p> <p>7 ovarian cancer?</p> <p>8 MS. MILLER: Objection.</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: I was asked to</p> <p>11 provide an opinion on talcum powder</p> <p>12 products. And my opinion, based on</p> <p>13 the epidemiologic literature, is that</p> <p>14 there is no causal association.</p> <p>15 So whatever is in talcum powder</p> <p>16 products would have come out in the</p> <p>17 literature.</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. Okay. Would it be fair to say</p> <p>20 you've never published any commentary or</p> <p>21 review of the literature on ovarian cancer</p> <p>22 and its causes generally? I apologize.</p> <p>23 A. I have never published a review</p> <p>24 on ovarian cancer.</p> <p>25 Q. Have you published a review on</p>
<p style="text-align: right;">Page 23</p> <p>1 A. However, if asbestos was</p> <p>2 present at all in a sufficient dose within</p> <p>3 talcum powder products, that would have come</p> <p>4 out in the epidemiologic literature, which it</p> <p>5 didn't.</p> <p>6 Q. Okay.</p> <p>7 A. Because the epidemiology shows</p> <p>8 that there is not a causal association</p> <p>9 between talcum powder and ovarian cancer.</p> <p>10 MR. TISI: I'm going to move to</p> <p>11 strike the answer as nonresponsive.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. My question was: Were you</p> <p>14 asked to offer a -- by the way, I'm not</p> <p>15 getting any -- I said -- my question was:</p> <p>16 Did you -- were you asked whether or not the</p> <p>17 presence of asbestos would provide a</p> <p>18 biologically plausible mechanism for talcum</p> <p>19 powder products causing ovarian cancer?</p> <p>20 The question is either yes or</p> <p>21 no.</p> <p>22 MR. LOCKE: Objection.</p> <p>23 THE WITNESS: Can you ask that</p> <p>24 question again?</p> <p>25</p>	<p style="text-align: right;">Page 25</p> <p>1 any cancer?</p> <p>2 A. We have a review in press --</p> <p>3 sorry, in submission on malignancies after</p> <p>4 lung transplantation.</p> <p>5 Q. Does it focus on whether or not</p> <p>6 talcum powder products is a risk factor for</p> <p>7 ovarian cancer?</p> <p>8 A. It does not.</p> <p>9 Q. Have you ever published a</p> <p>10 commentary or review on the causes of ovarian</p> <p>11 cancer?</p> <p>12 A. I have not.</p> <p>13 Q. Have you published a commentary</p> <p>14 or review on talcum powder products and its</p> <p>15 safety?</p> <p>16 A. I have not.</p> <p>17 Q. Have you published any</p> <p>18 commentary or review that deal with lifestyle</p> <p>19 or environmental cause of disease?</p> <p>20 MS. MILLER: Objection.</p> <p>21 THE WITNESS: That's a pretty</p> <p>22 broad question.</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. It is.</p> <p>25 A. I mean, you have my CV here,</p>

7 (Pages 22 to 25)

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<p style="text-align: right;">Page 26</p> <p>1 and my clinical and research experience has</p> <p>2 dealt with epidemiology. And the</p> <p>3 epidemiology -- epidemiology usually is the</p> <p>4 study of an exposure and how it relates to an</p> <p>5 outcome, and most of my papers and research</p> <p>6 has focused on exposures and how they lead to</p> <p>7 outcomes.</p> <p>8 Q. So what exposures,</p> <p>9 environmental or lifestyle exposures, have</p> <p>10 you investigated as related to what diseases?</p> <p>11 MS. MILLER: Objection.</p> <p>12 THE WITNESS: Well, you'd have</p> <p>13 to get a little more specific about</p> <p>14 what diseases we're talking about.</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. So my question was a broad one,</p> <p>17 because I don't see anything in your</p> <p>18 published literature that falls in this</p> <p>19 category, but it may just be that I missed</p> <p>20 it.</p> <p>21 Do you have any articles which</p> <p>22 deal with the relationship between lifestyle</p> <p>23 and environmental factors and any kind of</p> <p>24 cancer?</p> <p>25 A. That's a different question.</p>	<p style="text-align: right;">Page 28</p> <p>1 continue. So that environmental exposure can</p> <p>2 lead to an outcome over time.</p> <p>3 Q. But did you study the</p> <p>4 relationship between the exposure and the</p> <p>5 outcome, or was it primarily focused on lung</p> <p>6 transplant?</p> <p>7 A. Well, I --</p> <p>8 MS. MILLER: Objection.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Let me rephrase the question.</p> <p>11 Let me withdraw and rephrase the question.</p> <p>12 Did you do any causation</p> <p>13 analysis, including applying the Bradford</p> <p>14 Hill factors, to any exposure and any cancer</p> <p>15 in any of your publications?</p> <p>16 A. So in general, when a study is</p> <p>17 performed, we try to do either a Bradford</p> <p>18 Hill or different aspects of Bradford Hill to</p> <p>19 look at strength of associations or look at</p> <p>20 specificity, to look at consistency, to look</p> <p>21 at dose response. Sometimes it's available;</p> <p>22 sometimes it's not.</p> <p>23 I think it's a -- it's a --</p> <p>24 it's a framework that is often used in these</p> <p>25 papers and in these studies, but it's not</p>
<p style="text-align: right;">Page 27</p> <p>1 Q. Okay. So the answer would be?</p> <p>2 A. Well, I would have to say that</p> <p>3 the risk of malignancy after lung</p> <p>4 transplantation does deal with that.</p> <p>5 Q. Is lung transplantation an</p> <p>6 environmental or lifestyle?</p> <p>7 MS. MILLER: Objection.</p> <p>8 THE WITNESS: So again, that's</p> <p>9 a pretty broad question. It can be --</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. Okay.</p> <p>12 A. -- and it depends, because a</p> <p>13 lung transplant could be done for someone who</p> <p>14 is born with a disease, say like cystic</p> <p>15 fibrosis, a genetic disease, or a lung</p> <p>16 transplantation could be performed because</p> <p>17 someone has emphysema because they smoked all</p> <p>18 their life.</p> <p>19 And so the environmental</p> <p>20 exposure and the personal health exposure is</p> <p>21 very, very different in those two</p> <p>22 populations.</p> <p>23 Someone who's smoking may</p> <p>24 smoke -- continue to smoke after their lung</p> <p>25 transplant. It's not advised, but they may</p>	<p style="text-align: right;">Page 29</p> <p>1 necessarily the only thing that's done in</p> <p>2 them.</p> <p>3 Q. I understand.</p> <p>4 But if I looked at -- and I</p> <p>5 appreciate that. These may touch on aspects</p> <p>6 of Brad Hill -- the Bradford Hill guidelines.</p> <p>7 My question is: Did you ever,</p> <p>8 in any of these papers, synthesize all of the</p> <p>9 medical and scientific information available</p> <p>10 in order to do a Bradford Hill, complete</p> <p>11 Bradford Hill, analysis of the relationship</p> <p>12 between an exposure and a disease?</p> <p>13 MS. MILLER: Objection.</p> <p>14 THE WITNESS: Well, that's a</p> <p>15 very, very, very broad question.</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. Uh-huh.</p> <p>18 A. I think that there are certain</p> <p>19 papers in my CV that -- studies that we've</p> <p>20 done. It's the only study available that we</p> <p>21 did.</p> <p>22 Q. Okay.</p> <p>23 A. So, you know, it's impossible</p> <p>24 to synthesize everything that's in the</p> <p>25 medical literature if it's the only study</p>

8 (Pages 26 to 29)

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<p style="text-align: right;">Page 30</p> <p>1 that's done.</p> <p>2 Q. Okay. So if I -- it wouldn't</p> <p>3 be surprising if I looked at all these papers</p> <p>4 and the word "Bradford Hill" does not appear</p> <p>5 in any of them?</p> <p>6 A. That wouldn't be something that</p> <p>7 would appear --</p> <p>8 Q. Okay.</p> <p>9 A. -- normally in a paper like</p> <p>10 this.</p> <p>11 Q. Do any of these 78, 79 papers</p> <p>12 purport to provide any guidance or discussion</p> <p>13 of the definition or how to apply the</p> <p>14 Bradford Hill criteria, a theoretic paper,</p> <p>15 for example?</p> <p>16 MS. MILLER: Objection.</p> <p>17 THE WITNESS: I don't have any</p> <p>18 theoretical papers describing a</p> <p>19 Bradford Hill analysis.</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. Okay. So just -- this is a</p> <p>22 slightly different question than before.</p> <p>23 Have you ever published</p> <p>24 research aimed at elucidating a possible</p> <p>25 causation between a putative risk factor and</p>	<p style="text-align: right;">Page 32</p> <p>1 where you identified a risk factor for a</p> <p>2 disease?</p> <p>3 A. I can.</p> <p>4 I mean, one of the first</p> <p>5 studies that we did was to look at the risk</p> <p>6 factors for developing resistant bacteria in</p> <p>7 patients with cystic fibrosis.</p> <p>8 Q. Okay. In that context, did you</p> <p>9 apply the Bradford Hill guidelines?</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: Again, that's not</p> <p>12 really something that would have been</p> <p>13 done in that study.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Okay.</p> <p>16 A. There's a -- there's a large</p> <p>17 epidemiologic data set that the Cystic</p> <p>18 Fibrosis Foundation has, and we utilized that</p> <p>19 to identify factors that we thought might be</p> <p>20 important in seeing if those factors led to</p> <p>21 this resistant organism in that population.</p> <p>22 (Merlo Exhibit 3 marked for</p> <p>23 identification.)</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. I'm going to mark your report</p>
<p style="text-align: right;">Page 31</p> <p>1 disease?</p> <p>2 A. Well, I think that -- can you</p> <p>3 ask that again?</p> <p>4 Q. Yes.</p> <p>5 Have you ever published</p> <p>6 research aimed at elucidating possible</p> <p>7 causation between a putative risk factor and</p> <p>8 a disease?</p> <p>9 MS. MILLER: I'm objecting.</p> <p>10 Objection.</p> <p>11 THE WITNESS: So it's not -- we</p> <p>12 don't really approach epidemiologic</p> <p>13 studies trying to show causation with</p> <p>14 risk factors.</p> <p>15 Sometimes there are studies</p> <p>16 that are -- that we do just to</p> <p>17 identify risk factors. And then once</p> <p>18 risk factors are identified, then we</p> <p>19 could do follow-up studies to see if</p> <p>20 they are actual factors or exposures</p> <p>21 that lead to a certain outcome.</p> <p>22 Sometimes that takes multiple</p> <p>23 studies to do that.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. Can you identify an article</p>	<p style="text-align: right;">Page 33</p> <p>1 in this case.</p> <p>2 You issued a report in the</p> <p>3 talcum powder products litigation?</p> <p>4 A. I wrote a report.</p> <p>5 Q. Yes.</p> <p>6 A. Yes, I did.</p> <p>7 Q. Marked as Exhibit Number 3.</p> <p>8 A. Thank you.</p> <p>9 Q. Uh-huh.</p> <p>10 I think we've also been</p> <p>11 provided a supplemental materials reviewed</p> <p>12 and considered paper which I'll mark as 3A,</p> <p>13 which I assume is a supplement to your</p> <p>14 report.</p> <p>15 (Merlo Exhibit 3A marked for</p> <p>16 identification.)</p> <p>17 QUESTIONS BY MR. TISI:</p> <p>18 Q. Is this your report in this</p> <p>19 case, and are these the supplemental</p> <p>20 materials you reviewed as of today?</p> <p>21 A. This looks about correct.</p> <p>22 Q. Okay. Does this contain all</p> <p>23 the opinions you're prepared to offer in this</p> <p>24 case?</p> <p>25 MS. MILLER: Objection.</p>



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<p style="text-align: right;">Page 34</p> <p>1 THE WITNESS: From the -- from</p> <p>2 the items that I've reviewed thus far.</p> <p>3 There may be other things that come up</p> <p>4 in the literature, there may be other</p> <p>5 reports that are out, and I would like</p> <p>6 to review those and...</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. But as of today, as of today,</p> <p>9 this is -- these are your opinions and these</p> <p>10 are the bases of your opinions, correct?</p> <p>11 A. They are.</p> <p>12 Q. Okay. Go to page 30 of your</p> <p>13 report, if you would. The second sentence of</p> <p>14 your report says, "While there is no single</p> <p>15 method for undertaking a causal assessment</p> <p>16 based on epidemiology, the criteria</p> <p>17 formulated by Austin Bradford Hill are often</p> <p>18 used and are considered the gold standard for</p> <p>19 evaluating causation once an association has</p> <p>20 been identified."</p> <p>21 Do you see that?</p> <p>22 A. I do.</p> <p>23 Q. Can you point to any articles</p> <p>24 on your CV where you applied the gold</p> <p>25 standard articulated on page 30 of your</p>	<p style="text-align: right;">Page 36</p> <p>1 MS. MILLER: Objection.</p> <p>2 THE WITNESS: I wouldn't say it</p> <p>3 that way.</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. I understand you wouldn't say</p> <p>6 it that way, but in concept.</p> <p>7 A. In concept.</p> <p>8 That's the concept of all of</p> <p>9 those articles, or at least the majority of</p> <p>10 them, that we're looking for -- we're looking</p> <p>11 at an outcome, and we're looking for an</p> <p>12 exposure to see if that exposure leads to an</p> <p>13 outcome.</p> <p>14 And there are considerations</p> <p>15 that we consciously or subconsciously -- "we"</p> <p>16 meaning my research team and myself</p> <p>17 consciously and subconsciously --</p> <p>18 considerations that Bradford Hill put forth</p> <p>19 that we apply in there.</p> <p>20 Now, is it stated? No, but it</p> <p>21 wouldn't be stated in the papers. The</p> <p>22 medical literature is not written that like</p> <p>23 that.</p> <p>24 Q. Okay. You mentioned -- and you</p> <p>25 give an example in your report; we're going</p>
<p style="text-align: right;">Page 35</p> <p>1 report?</p> <p>2 MS. MILLER: Objection.</p> <p>3 THE WITNESS: Well, again, most</p> <p>4 of these articles are epidemiologic</p> <p>5 studies looking at an exposure and an</p> <p>6 outcome.</p> <p>7 Sometimes there are Bradford</p> <p>8 Hill considerations that are</p> <p>9 available, and sometimes there are</p> <p>10 not.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. But whether they are -- I'm</p> <p>13 sorry, go ahead.</p> <p>14 A. And in every study, we apply</p> <p>15 what we can --</p> <p>16 Q. Right.</p> <p>17 A. -- based on these suggestions</p> <p>18 put forth by Bradford Hill.</p> <p>19 Q. Is there any study in which you</p> <p>20 say, "We are undertaking" -- and I'm not</p> <p>21 using these words specifically.</p> <p>22 "We are, in this article,</p> <p>23 undertaking a causal assessment of putative</p> <p>24 factor X and disease Y, and here is my</p> <p>25 analysis"?</p>	<p style="text-align: right;">Page 37</p> <p>1 to talk about it later -- primary pulmonary</p> <p>2 hypertension and anorexigens.</p> <p>3 Do you remember the IPPHS</p> <p>4 study?</p> <p>5 A. I do.</p> <p>6 Q. Does, in your opinion, exposure</p> <p>7 to anorexigens cause pulmonary hypertension,</p> <p>8 primary pulmonary hypertension?</p> <p>9 A. The opinion of the medical</p> <p>10 community -- and part of that is that a</p> <p>11 significant exposure over a significant</p> <p>12 amount of time with certain specific</p> <p>13 anorexigens is associated with pulmonary</p> <p>14 hypertension.</p> <p>15 Q. That's a different -- that's a</p> <p>16 different question than I'm asking, Doctor.</p> <p>17 So I asked you -- I asked you</p> <p>18 whether or not in your opinion exposure to</p> <p>19 anorexigens, in particular dexfenfluramine</p> <p>20 and fenfluramine, cause pulmonary</p> <p>21 hypertension?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: So I'm going to</p> <p>24 answer it very similarly, because</p> <p>25 you --</p>

10 (Pages 34 to 37)



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<p style="text-align: right;">Page 38</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. But I'm using the word "cause,"</p> <p>3 so --</p> <p>4 A. And based on the medical</p> <p>5 literature and based on clinical experience,</p> <p>6 if we're talking about those two anorexigens,</p> <p>7 the opinion of the medical community is that</p> <p>8 those cause primary pulmonary hypertension.</p> <p>9 Q. Okay. Is that your opinion?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. And we'll talk about it</p> <p>12 again, but there was only one study,</p> <p>13 epidemiologic study, the IPPHS study,</p> <p>14 correct?</p> <p>15 A. You'd have to show me what</p> <p>16 you're referring to so we can look at it.</p> <p>17 Q. Yeah, it's the study by</p> <p>18 Abenheim. I believe it's footnote 77 of your</p> <p>19 report.</p> <p>20 You know that study, don't you?</p> <p>21 A. I referenced it, but if you'd</p> <p>22 like to discuss it --</p> <p>23 Q. I'm not going to discuss --</p> <p>24 A. -- I'd like to see it in front</p> <p>25 of me to discuss it.</p>	<p style="text-align: right;">Page 40</p> <p>1 hypertension expert, so if you'd like to</p> <p>2 discuss that, I would need to review the</p> <p>3 medical literature.</p> <p>4 Q. Okay.</p> <p>5 A. I can't agree or disagree with</p> <p>6 you.</p> <p>7 Q. Well, you're not an ovarian</p> <p>8 cancer expert, are you?</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: I think I</p> <p>11 answered that before.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. If you're not a primary</p> <p>14 pulmonary hypertension expert, and that's a</p> <p>15 lung disease, are you a -- do you consider</p> <p>16 yourself an ovarian cancer expert?</p> <p>17 MR. LOCKE: Objection.</p> <p>18 THE WITNESS: And what I said</p> <p>19 before is that there are certain</p> <p>20 aspects of cancer that I do consider</p> <p>21 myself an expert, and that is the care</p> <p>22 of patients who have cancer in the</p> <p>23 intensive care unit.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. Okay. Do you hold yourself out</p>
<p style="text-align: right;">Page 39</p> <p>1 Q. I will discuss it later and</p> <p>2 I'll -- I will discuss it later, but I'm</p> <p>3 asking you: Do you know that there was only</p> <p>4 one study, epidemiologic study, performed?</p> <p>5 MS. MILLER: Objection.</p> <p>6 THE WITNESS: I'm not aware of</p> <p>7 that, but if we're going to talk about</p> <p>8 studies, then I would have like to</p> <p>9 have that in front of me.</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. I'm going to give it to you.</p> <p>12 I'm asking you whether there</p> <p>13 are any other studies, epidemiologic studies,</p> <p>14 that you're aware of other than that study,</p> <p>15 which I will give you.</p> <p>16 MR. LOCKE: Objection.</p> <p>17 MS. MILLER: Objection.</p> <p>18 THE WITNESS: You know, I'm not</p> <p>19 really here to give my opinion on</p> <p>20 whether or not there was one or ten</p> <p>21 epidemiologic studies looking at</p> <p>22 anorexigens in pulmonary hypertension.</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. I understand.</p> <p>25 A. I'm not a pulmonary</p>	<p style="text-align: right;">Page 41</p> <p>1 to your colleagues as an expert in ovarian</p> <p>2 cancer?</p> <p>3 MS. MILLER: Objection.</p> <p>4 MR. LOCKE: Objection.</p> <p>5 THE WITNESS: I'm going to have</p> <p>6 to answer that very similarly because</p> <p>7 there are certain aspects of</p> <p>8 malignancies where I have taken care</p> <p>9 of patients with ovarian cancer in the</p> <p>10 intensive care unit, who are very,</p> <p>11 very sick, who have been given</p> <p>12 specific therapies for their ovarian</p> <p>13 cancer, that I do consider myself an</p> <p>14 expert in taking care of.</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. I understand that.</p> <p>17 But ovarian cancer is a -- let</p> <p>18 me just -- if I was, you know, a doctor at</p> <p>19 Hopkins, and we're not sitting here in a</p> <p>20 deposition, and I came to you and said,</p> <p>21 "Doctor, what is your area of expertise?"</p> <p>22 would you say "ovarian cancer"?</p> <p>23 MS. MILLER: Objection.</p> <p>24 MR. LOCKE: Objection. Asked</p> <p>25 and answered four times.</p>

11 (Pages 38 to 41)

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<p>1 THE WITNESS: I would say</p> <p>2 internal medicine. I would say</p> <p>3 pulmonary medicine. I would say</p> <p>4 critical care medicine. And all of</p> <p>5 those -- well, maybe -- no, actually</p> <p>6 all of them encompass taking care of</p> <p>7 patients who can become or do become</p> <p>8 very, very sick with ovarian cancer</p> <p>9 and with specific -- and having</p> <p>10 specific expertise in taking care of</p> <p>11 some of the medicines that they get</p> <p>12 that give them very, very specific</p> <p>13 side effects.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Have you also cared for</p> <p>16 patients with primary pulmonary hypertension?</p> <p>17 A. I have.</p> <p>18 Q. Okay. So does that also make</p> <p>19 you an expert in the area of primary</p> <p>20 pulmonary hypertension?</p> <p>21 A. So there are certain aspects of</p> <p>22 primary pulmonary hypertension that I do</p> <p>23 consider myself an expert in. I do take care</p> <p>24 of patients in the hospital who have primary</p> <p>25 pulmonary hypertension and also secondary</p>	<p>1 the market for quite some time, so it</p> <p>2 would be very rare to see somebody who</p> <p>3 had a new diagnosis of pulmonary</p> <p>4 hypertension and an exposure to one of</p> <p>5 those medicines.</p> <p>6 When I'm evaluating someone</p> <p>7 with pulmonary hypertension, I</p> <p>8 typically do ask them about the</p> <p>9 potential exposures to anorexigens.</p> <p>10 It's just on the list of things to do.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Okay.</p> <p>13 A. And it should be part of the</p> <p>14 differential diagnosis.</p> <p>15 Q. So you're treating -- is it</p> <p>16 fair to say that with ovarian cancer you're</p> <p>17 treating the sequela of the disease, not</p> <p>18 making the diagnosis of the disease?</p> <p>19 A. No, I mean, I've probably made</p> <p>20 the diagnosis of disease one or two times in</p> <p>21 my career.</p> <p>22 Q. Okay. And how long -- when you</p> <p>23 say your career, how long is that?</p> <p>24 A. I graduated medical school in</p> <p>25 1996, so that's when I became a doctor.</p>
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<p>1 pulmonary hypertension.</p> <p>2 But -- I'll just stop there.</p> <p>3 Q. Do you put -- when you're</p> <p>4 taking care of a patient with primary</p> <p>5 pulmonary hypertension and they're exposed to</p> <p>6 anorexigens, or they're exposed to</p> <p>7 fenfluramine, dexfenfluramine, although those</p> <p>8 are off the market, and would you note that</p> <p>9 on the list of potential differential causes</p> <p>10 of the pulmonary hypertension?</p> <p>11 MS. MILLER: Objection.</p> <p>12 THE WITNESS: Can you ask that</p> <p>13 again?</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Yes.</p> <p>16 If you have a patient who has</p> <p>17 primary pulmonary hypertension with a history</p> <p>18 of use of the anorexigens fenfluramine and</p> <p>19 dexfenfluramine, do you put them on the list</p> <p>20 of potential causes in your -- do you make</p> <p>21 note of that in your record?</p> <p>22 MS. MILLER: Objection.</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: Well, you're</p> <p>25 right, these medicines have been off</p>	<p>1 Q. Okay. So can you -- you list</p> <p>2 the factors on page 30 of your report, the</p> <p>3 Bradford Hill factors: strength of</p> <p>4 association, consistency, specificity,</p> <p>5 temporality, biologic gradient, plausibility,</p> <p>6 coherence, experimentation, analogy.</p> <p>7 You list them all, correct?</p> <p>8 A. One, two, three, four, five,</p> <p>9 six, seven, eight, nine. Yes, correct.</p> <p>10 Q. Okay. From the time that</p> <p>11 Bradford Hill, Sir Bradford Hill, wrote his</p> <p>12 article -- and you agree that's a seminal</p> <p>13 paper on the topic of how you evaluate cause?</p> <p>14 A. It's an article, and it's an</p> <p>15 important article historically. We learn</p> <p>16 about it in epidemiology classes. I teach</p> <p>17 about it.</p> <p>18 Seminal article, I mean, there</p> <p>19 are lots of articles that are written about</p> <p>20 causation. This is an article that I've</p> <p>21 learned about in class and I've taught about</p> <p>22 in class.</p> <p>23 Q. Well, I think you used the word</p> <p>24 "seminal" in your report, didn't you?</p> <p>25 A. I may have.</p>

12 (Pages 42 to 45)

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<p>1 Q. Okay.</p> <p>2 A. If you can show me that, I --</p> <p>3 Q. So, well, do you agree that</p> <p>4 it's --</p> <p>5 A. I don't know where.</p> <p>6 Q. -- it's a seminal article on</p> <p>7 the issue?</p> <p>8 A. But can you show me where I</p> <p>9 said that?</p> <p>10 Q. I'm asking what your opinion</p> <p>11 is as to whether or not you agree that's the</p> <p>12 seminal article -- that's a seminal article</p> <p>13 on causation.</p> <p>14 A. But you said I --</p> <p>15 Q. I'm not asking you whether you</p> <p>16 said it in the report.</p> <p>17 A. You just did.</p> <p>18 MS. MILLER: Objection.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. I'm asking you -- I'm asking</p> <p>21 you whether it is a seminal article.</p> <p>22 A. And I'll say, it's -- it is an</p> <p>23 article about -- written about causation.</p> <p>24 Q. Okay. Has the medical</p> <p>25 community, over the past 60 years, changed</p>	<p>1 I'm asking you: In your</p> <p>2 view -- let me -- in terms of you, Dr. Merlo,</p> <p>3 do you apply the same -- is your definitions</p> <p>4 of the Bradford Hill factors the same in 2019</p> <p>5 as described by Bradford Hill in 1965?</p> <p>6 A. I would say that it's very</p> <p>7 similar --</p> <p>8 Q. Okay.</p> <p>9 A. -- to what's described.</p> <p>10 Q. Is there any that are different</p> <p>11 in your view?</p> <p>12 Can you look at it and say, for</p> <p>13 example, "My view of the coherence factor is</p> <p>14 different than as described by Dr. -- by</p> <p>15 Bradford Hill"?</p> <p>16 MS. MILLER: Objection.</p> <p>17 For the record, I'll just state</p> <p>18 that the -- Dr. Merlo brought Bradford</p> <p>19 Hill with him.</p> <p>20 MR. TISI: I'm going to mark it</p> <p>21 as well.</p> <p>22 MS. MILLER: Do you want to</p> <p>23 mark this one?</p> <p>24 MR. TISI: I will not. I'll</p> <p>25 mark them when I get --</p>
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<p>1 the definitions of any of the Bradford Hill</p> <p>2 factors as described by Bradford Hill in his</p> <p>3 1965 article?</p> <p>4 MS. MILLER: Objection.</p> <p>5 THE WITNESS: That is a very</p> <p>6 general question, and I would have to</p> <p>7 say that it depends. It depends on</p> <p>8 who you're defining as the medical</p> <p>9 community, who you're defining as --</p> <p>10 yeah, I mean, that's a -- too general</p> <p>11 a question to answer.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. Well, are there different --</p> <p>14 do -- does the medical community define these</p> <p>15 factors differently depending upon who's</p> <p>16 applying them?</p> <p>17 MS. MILLER: Objection.</p> <p>18 THE WITNESS: Again, I don't</p> <p>19 know who you're referring to as far as</p> <p>20 the medical community. You'd have to</p> <p>21 be much more specific about that.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Well, you used the term,</p> <p>24 Doctor. I'm just kind of jumping off of what</p> <p>25 you said.</p>	<p>1 MS. MILLER: But he's looking</p> <p>2 at it now.</p> <p>3 MR. TISI: He can look at it.</p> <p>4 I think you're limited to "objection,"</p> <p>5 and if we start with this, we're going</p> <p>6 to go to the judge.</p> <p>7 MS. SHARKO: Mr. Tisi --</p> <p>8 MR. TISI: And that's another</p> <p>9 thing. We're only having one</p> <p>10 objection.</p> <p>11 MS. SHARKO: You don't need to</p> <p>12 point your finger.</p> <p>13 MR. TISI: I pointed up. I</p> <p>14 pointed up, Counsel, and the record</p> <p>15 will reflect that I did. There's a</p> <p>16 camera right on me, as you assured me.</p> <p>17 And you're laughing, let the</p> <p>18 record reflect that, as you do in</p> <p>19 every deposition.</p> <p>20 MS. SHARKO: Please, behave</p> <p>21 yourself.</p> <p>22 MR. TISI: Agreed.</p> <p>23 THE WITNESS: So did you have a</p> <p>24 specific question about coherence?</p> <p>25</p>

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<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. No.</p> <p>3 My question is -- I want to be</p> <p>4 able to say -- I want to know whether or not</p> <p>5 your 2009 {sic} definitions of the Bradford</p> <p>6 Hill factors -- no, let me phrase it a</p> <p>7 different way.</p> <p>8 Do you take any issue with any</p> <p>9 of the factors as described in the 1965</p> <p>10 articles and say, you know, "This concept is</p> <p>11 outdated, I would define it differently," or</p> <p>12 can we look at the 1965 factors as being the</p> <p>13 ones you actually apply, the definitions you</p> <p>14 use?</p> <p>15 A. So I usually look at them as</p> <p>16 considerations and not factors.</p> <p>17 Q. Okay.</p> <p>18 A. And in general, the way it's</p> <p>19 written is how I interpret and move through</p> <p>20 when I evaluate evidence.</p> <p>21 Q. Okay. Now, almost every one of</p> <p>22 your 79 peer-reviewed papers going back to</p> <p>23 your CV have to do with lung disease of one</p> <p>24 kind or another, correct?</p> <p>25 A. There are a few that deal with</p>	<p>1 MS. MILLER: Objection.</p> <p>2 MR. LOCKE: Objection.</p> <p>3 MS. MILLER: Asked and answered</p> <p>4 again.</p> <p>5 THE WITNESS: I mean, I don't</p> <p>6 even know what vast majority means,</p> <p>7 but --</p> <p>8 QUESTIONS BY MR. TISI:</p> <p>9 Q. I would say -- let's say more</p> <p>10 than 50 percent.</p> <p>11 MS. MILLER: Objection to the</p> <p>12 definition of "vast majority" as more</p> <p>13 than 50 percent.</p> <p>14 THE WITNESS: So, again, I</p> <p>15 don't know the numbers. We can go</p> <p>16 through them if you'd like --</p> <p>17 QUESTIONS BY MR. TISI:</p> <p>18 Q. Okay.</p> <p>19 A. -- and get a percentage, but --</p> <p>20 Q. I think -- I think -- fine.</p> <p>21 On your CV at the bottom of</p> <p>22 page 8 you've written several book chapters,</p> <p>23 correct?</p> <p>24 A. Book chapters, sure.</p> <p>25 Q. Do any deal with cancer?</p>
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<p>1 certain conditions that may not involve lung</p> <p>2 disease.</p> <p>3 Q. The vast majority are, correct?</p> <p>4 A. I mean, I haven't tallied up.</p> <p>5 I don't know percentages, but there are</p> <p>6 articles in there that involve other disease</p> <p>7 states.</p> <p>8 Q. The vast -- would you agree</p> <p>9 that the vast majority of your published</p> <p>10 literature deals with lung disease of one</p> <p>11 kind or another, whether it be transplants,</p> <p>12 cystic fibrosis, COPD, et cetera?</p> <p>13 MS. MILLER: Objection. Asked</p> <p>14 and answered.</p> <p>15 THE WITNESS: I didn't tally it</p> <p>16 up, and I don't have the percentages,</p> <p>17 but I do know that there are many</p> <p>18 articles in there that are written</p> <p>19 about diseases that may not involve</p> <p>20 the lungs.</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. I don't think you have to tally</p> <p>23 them up to look at them and see that the vast</p> <p>24 majority of them deal with lung diseases,</p> <p>25 true?</p>	<p>1 A. I don't specifically recall,</p> <p>2 but in this First Aid for Internal Medicine</p> <p>3 Boards there may have been -- there may have</p> <p>4 been some -- some cancer topics in there.</p> <p>5 Q. Do any deal with the</p> <p>6 methodology for assessing causation?</p> <p>7 A. Book chapters on the</p> <p>8 methodology assessing causation? Not that</p> <p>9 I'm aware of.</p> <p>10 Q. Any deal with talcum powder or</p> <p>11 ovarian cancer?</p> <p>12 A. You know, other than the</p> <p>13 potential for there being talk about</p> <p>14 malignancies or cancer in First Aid for</p> <p>15 Internal Medicine Boards, which I don't</p> <p>16 specifically recall.</p> <p>17 Q. Do you think that that</p> <p>18 references talcum powder?</p> <p>19 A. Do I think that what references</p> <p>20 talcum powder?</p> <p>21 Q. That first chapter.</p> <p>22 A. Which one? I'm --</p> <p>23 MS. MILLER: Objection.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. The one you just mentioned.</p>

14 (Pages 50 to 53)

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<p style="text-align: right;">Page 54</p> <p>1 Do any of your book chapters</p> <p>2 deal in any way with talcum powder?</p> <p>3 A. No, they don't.</p> <p>4 Q. Okay. Prior to finalizing your</p> <p>5 report in February of 2019, two months ago,</p> <p>6 had you ever publicly expressed your opinion</p> <p>7 about talcum powder and ovarian cancer?</p> <p>8 A. No.</p> <p>9 Q. Now, we talked about the fact</p> <p>10 that you were an associate professor at Johns</p> <p>11 Hopkins critical care.</p> <p>12 You've been associate professor</p> <p>13 for how many years?</p> <p>14 A. I'd have to look back at my CV.</p> <p>15 It looks like I was promoted to associate</p> <p>16 professor in 2015.</p> <p>17 Q. So you've been associate</p> <p>18 professor for four years?</p> <p>19 A. That's correct.</p> <p>20 (Merlo Exhibit 4 marked for</p> <p>21 identification.)</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Okay. I want to show you</p> <p>24 Exhibit Number 4, which is the -- your bio on</p> <p>25 your web page for the critical care division</p>	<p style="text-align: right;">Page 56</p> <p>1 Q. Any mention of cancer of any</p> <p>2 kind?</p> <p>3 A. There is not.</p> <p>4 Q. Okay. Now, your CV also</p> <p>5 mentions that you currently run the adult</p> <p>6 clinic for a cystic fibrosis center for the</p> <p>7 past four years, since 2015?</p> <p>8 A. So I'm the associate program</p> <p>9 director for our adult cystic fibrosis</p> <p>10 program at Johns Hopkins.</p> <p>11 Q. I'm sorry, I promoted you.</p> <p>12 A. Thank you. It's very difficult</p> <p>13 to get promoted at Hopkins, so --</p> <p>14 Q. Maybe someday.</p> <p>15 You've held that position since</p> <p>16 2015?</p> <p>17 A. Where are you referring --</p> <p>18 where are we looking now?</p> <p>19 Q. Page 2.</p> <p>20 A. Page 2.</p> <p>21 Q. I'm sorry, the first page.</p> <p>22 A. First page.</p> <p>23 Q. It says, "2015 to present,</p> <p>24 associate program director, Adult Cystic</p> <p>25 Fibrosis Center."</p>
<p style="text-align: right;">Page 55</p> <p>1 of Hopkins.</p> <p>2 That's your picture, correct?</p> <p>3 A. That is my picture.</p> <p>4 Q. Does it list your expertise as</p> <p>5 cystic fibrosis, lung transplant, pulmonary</p> <p>6 and critical care medicine?</p> <p>7 A. Are you referring to up top --</p> <p>8 Q. Yes.</p> <p>9 A. -- to the right?</p> <p>10 Expertise: cystic fibrosis,</p> <p>11 lung transplant, pulmonary and critical care</p> <p>12 medicine --</p> <p>13 Q. Yes.</p> <p>14 A. -- pulmonary?</p> <p>15 Q. Yeah.</p> <p>16 A. That's what it says.</p> <p>17 Q. Does it also say your research</p> <p>18 interests are HIV-related pulmonary disease,</p> <p>19 outcomes after lung transplantation, clinics</p> <p>20 and -- clinical cystic fibrosis?</p> <p>21 A. That's what it says.</p> <p>22 Q. Okay. Any mention of ovarian</p> <p>23 cancer?</p> <p>24 A. There is no mention of ovarian</p> <p>25 cancer.</p>	<p style="text-align: right;">Page 57</p> <p>1 A. 2015, yes, that's correct.</p> <p>2 Q. So for four years you've been</p> <p>3 an associate professor. For four years</p> <p>4 you've been an associate program director for</p> <p>5 the Cystic Fibrosis Clinic.</p> <p>6 What is cystic fibrosis?</p> <p>7 A. Cystic fibrosis is a genetic</p> <p>8 disease that -- some people are born with it,</p> <p>9 and it leads to an abnormal chloride channel</p> <p>10 in epithelial-lined cells -- in</p> <p>11 epithelial-lined organs in the body. In the</p> <p>12 lungs it leads to a buildup of secretions and</p> <p>13 progressive lung disease that oftentimes</p> <p>14 leads to death or lung transplantation.</p> <p>15 It leads to sinus disease. It</p> <p>16 leads to liver disease. It leads to problems</p> <p>17 in the gastrointestinal tract. It leads to</p> <p>18 infertility in men. It leads to women</p> <p>19 oftentimes having difficulties getting</p> <p>20 pregnant.</p> <p>21 And, unfortunately, there is no</p> <p>22 cure for it.</p> <p>23 Q. Is it cancer?</p> <p>24 A. No.</p> <p>25 (Merlo Exhibit 5 marked for</p>

15 (Pages 54 to 57)



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<p style="text-align: right;">Page 58</p> <p>1 identification.)</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Okay. If I could show you</p> <p>4 Exhibit Number 5, which is the web page from</p> <p>5 the Adult Clinic for the Cystic Fibrosis</p> <p>6 Center.</p> <p>7 A. I look much younger there.</p> <p>8 Q. We all look younger, Doctor, at</p> <p>9 different times.</p> <p>10 This is your web page from the</p> <p>11 Johns Hopkins Adult Clinic for Cystic</p> <p>12 Fibrosis?</p> <p>13 A. It's a web page from Hopkins.</p> <p>14 I don't know whose web page it is. I didn't</p> <p>15 make it.</p> <p>16 Q. And it lists you and it -- an</p> <p>17 associate professor of medicine and</p> <p>18 epidemiology, correct? Right under your</p> <p>19 name?</p> <p>20 A. Where are you referring to?</p> <p>21 Q. Right under your name.</p> <p>22 A. I see.</p> <p>23 Associate professor of medicine</p> <p>24 and epidemiology, yes.</p> <p>25 Q. And I will talk about the</p>	<p style="text-align: right;">Page 60</p> <p>1 THE WITNESS: On this website,</p> <p>2 it's listed that my clinical interests</p> <p>3 are cystic fibrosis and lung</p> <p>4 transplantation.</p> <p>5 But again, I have no idea who</p> <p>6 put this together. I don't know if</p> <p>7 they were my colleagues or they're --</p> <p>8 some random person at Hopkins did</p> <p>9 this.</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. Okay. Did you ever ask to take</p> <p>12 it down?</p> <p>13 A. No.</p> <p>14 Q. Okay. Would you ever tell</p> <p>15 somebody, "let's put in my clinical interests</p> <p>16 here treatment of ovarian cancer"?</p> <p>17 MS. MILLER: Objection.</p> <p>18 THE WITNESS: You know, there</p> <p>19 are lots of websites out there, and if</p> <p>20 I spent my time just looking at</p> <p>21 websites, I wouldn't be able to get</p> <p>22 anything done.</p> <p>23 So Hopkins has a lot of web</p> <p>24 presence, and we oftentimes don't know</p> <p>25 what goes up there.</p>
<p style="text-align: right;">Page 59</p> <p>1 epidemiology portion of it, but right now let</p> <p>2 me ask you this: The research interests</p> <p>3 listed here are outcomes of adults with</p> <p>4 cystic fibrosis infected with multiple</p> <p>5 antibiotic-resistant pneumonias -- and I</p> <p>6 don't even know how to pronounce that last</p> <p>7 word.</p> <p>8 Could you tell me?</p> <p>9 A. Pseudomonas aeruginosa.</p> <p>10 Q. Okay. Diagnosis of management</p> <p>11 of pulmonary arterial venous malformations,</p> <p>12 correct?</p> <p>13 A. I do see that.</p> <p>14 Q. Are there areas of your</p> <p>15 research interests?</p> <p>16 A. Those are things that I've been</p> <p>17 interested in in research, among other</p> <p>18 things. I don't know who put this together</p> <p>19 or where they got those things, so -- but</p> <p>20 that's part of my research interests, sure.</p> <p>21 Q. Your clinical interests, at</p> <p>22 least as described by your colleagues at</p> <p>23 Johns Hopkins, are cystic fibrosis and lung</p> <p>24 transplantation, correct?</p> <p>25 MS. MILLER: Objection.</p>	<p style="text-align: right;">Page 61</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. I'll just start: Now that</p> <p>3 you've seen it, would you go back to your</p> <p>4 colleagues and say, "You know something, I'm</p> <p>5 an expert in ovarian cancer; you need to list</p> <p>6 that"?</p> <p>7 MS. MILLER: Objection.</p> <p>8 MR. LOCKE: Objection.</p> <p>9 THE WITNESS: No.</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. Okay.</p> <p>12 A. Not on a website.</p> <p>13 Q. Now let's talk a bit about your</p> <p>14 appointment as associate professor of</p> <p>15 medicine and epidemiology at the Johns</p> <p>16 Hopkins School of Public Health.</p> <p>17 You held that position as well,</p> <p>18 right?</p> <p>19 A. Can you say that one more time?</p> <p>20 Q. Yeah.</p> <p>21 Do you hold -- are you -- have</p> <p>22 you been appointed as associate professor of</p> <p>23 medicine and epidemiology at the Johns</p> <p>24 Hopkins School of Public Health?</p> <p>25 A. So I'm appointed an associate</p>

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<p style="text-align: right;">Page 62</p> <p>1 professor of epidemiology at the Johns 2 Hopkins Bloomberg School of Public Health. 3 Q. Now, would you agree that your 4 primary appointment, in terms of the time you 5 spend, is in the pulmonary and critical care 6 area as opposed to the School of Public 7 Health? 8 MS. MILLER: Objection. 9 THE WITNESS: So it depends. 10 It depends on the time of year. It 11 depends on year to year. There may be 12 more -- there may be some years where 13 I spend much more time over at the 14 School of Public Health in 15 collaborating with the epidemiologists 16 over there. There may be years or 17 months where I spend more time in the 18 hospital. There's no way for me to 19 really parse it out. 20 QUESTIONS BY MR. TISI: 21 Q. If you were to -- if you were 22 to -- let's take a year, but we could take 23 four years you've been associate professor. 24 Let's do the big picture first. 25 Over the four years you have</p>	<p style="text-align: right;">Page 64</p> <p>1 for you, this and that. 2 So there's no way for me to 3 parse out whether it's 20/80, 80/20, 4 50/50. It's all related. 5 QUESTIONS BY MR. TISI: 6 Q. Do you have an office over at 7 the School of Public Health? 8 A. I don't have a physical space 9 over at the School of Public Health. 10 Q. Okay. 11 A. I do have -- I do have lab 12 meetings that are located over at the School 13 of Public Health or in other epidemiologic 14 areas that are outside the School of 15 Medicine. 16 Q. Now, there are professors and 17 assistant professors who work only in the 18 Bloomberg School of Public Health, correct? 19 A. There are faculty that are only 20 appointed -- their only appointment is within 21 the School of Public Health, that is correct. 22 Q. And they spend all their 23 professional time in that school -- in the 24 School of Public Health? 25 A. Not necessarily.</p>
<p style="text-align: right;">Page 63</p> <p>1 been at Hopkins, and you had to give me an 2 estimate of the time you spend over at the 3 Bloomberg School of Public Health as opposed 4 to at the pulmonary and critical care 5 medicine or the cystic fibrosis clinic, 6 basically the Bloomberg School of Public 7 Health and everything else, how would you 8 divide the time over the past four years? 9 MR. LOCKE: Objection. 10 THE WITNESS: I think it's 11 impossible to divide it because I may 12 go to clinic on, say, Wednesday -- 13 Thursday and see transplant patients 14 and see cystic fibrosis patients, but 15 then Friday I'll spend working on a 16 research project with one of my 17 fellows where we have some of the 18 epidemiologists and analysts helping 19 us with our analysis and study 20 designs. 21 There may be times when I'm 22 seeing a patient in clinic, and then I 23 call one of my colleagues over at the 24 School of Public Health because I'm 25 going to say I'm going to get a sample</p>	<p style="text-align: right;">Page 65</p> <p>1 Q. Okay. 2 A. Because Hopkins is a very 3 collaborative place, and even though a 4 faculty member may not have a primary 5 appointment within a school, that doesn't 6 necessarily mean that that person would spend 7 his or her time only in one specific 8 building. 9 Q. Now -- 10 A. It's a very fluid place. 11 Q. Okay. But there are full 12 professors at the Bloomberg School of Public 13 Health, correct? 14 A. There are full professors at 15 the Johns Hopkins Bloomberg School of Public 16 Health. 17 Q. And there are full associate 18 professors at -- full-time associate 19 professors at the Bloomberg School of Public 20 Health? 21 A. There are full-time associate 22 professors at the Bloomberg School of Public 23 Health. 24 (Merlo Exhibit 6 marked for 25 identification.)</p>

17 (Pages 62 to 65)

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<p style="text-align: right;">Page 66</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. I'm going to provide you as</p> <p>3 Exhibit Number 6 the faculty directory at the</p> <p>4 Bloomberg School of -- the epidemiology</p> <p>5 department at the Bloomberg School of Public</p> <p>6 Health.</p> <p>7 MS. MILLER: Are you providing</p> <p>8 it to the rest of us or just to him?</p> <p>9 MR. TISI: I apologize,</p> <p>10 Counsel. I didn't do it quick enough</p> <p>11 for you.</p> <p>12 MS. MILLER: Thank you.</p> <p>13 MR. TISI: Actually, may I have</p> <p>14 one copy back?</p> <p>15 MS. MILLER: Totally.</p> <p>16 MR. TISI: Thank you.</p> <p>17 MS. MILLER: Susan and I can</p> <p>18 share.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. I'll represent to you, Doctor,</p> <p>21 that this is the faculty directory of the</p> <p>22 epidemiology department, Bloomberg School of</p> <p>23 Public Health. It was taken off the website</p> <p>24 before your deposition was moved last week,</p> <p>25 so April 3rd of 2019.</p>	<p style="text-align: right;">Page 68</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. And it's used at Hopkins,</p> <p>3 right?</p> <p>4 A. Dr. Gordis' textbook, when I</p> <p>5 took the course, was used at Hopkins.</p> <p>6 I'm not sure what textbook is</p> <p>7 used for that specific class today.</p> <p>8 Q. And do you know a Dr. -- and I</p> <p>9 can't pronounce his name -- Moyses Szklo?</p> <p>10 A. Yeah, and I -- I'm not sure how</p> <p>11 to pronounce his last -- his last name</p> <p>12 either.</p> <p>13 Q. He's a full professor -- he's a</p> <p>14 full professor of epidemiology, correct?</p> <p>15 A. Moyses Szklo.</p> <p>16 Do I know him? No. I know of</p> <p>17 him.</p> <p>18 Q. Do you know that he took over</p> <p>19 the editing of the book when -- on</p> <p>20 epidemiology when Dr. Gordis passed?</p> <p>21 A. I don't know that.</p> <p>22 Q. Okay. Both of those</p> <p>23 epidemiologists I mentioned, Dr. Szklo and</p> <p>24 Dr. Gordis, were full-time professors at</p> <p>25 the -- or in Dr. Szklo's case still is a</p>
<p style="text-align: right;">Page 67</p> <p>1 Do you see that?</p> <p>2 A. I do.</p> <p>3 MR. LOCKE: Objection.</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. And it lists full-time faculty.</p> <p>6 Do you see that?</p> <p>7 A. I don't --</p> <p>8 Q. See on the top -- top right</p> <p>9 here, full time?</p> <p>10 A. I do see that.</p> <p>11 Q. And if you look through here --</p> <p>12 first of all, actually on the front page is a</p> <p>13 gentleman by the name of Leon Gordis.</p> <p>14 Who is Dr. Gordis?</p> <p>15 A. Leon Gordis was an</p> <p>16 epidemiologist who -- when I took</p> <p>17 Epidemiology I at the School of Public</p> <p>18 Health, he taught the course.</p> <p>19 Q. And he is -- he wrote a</p> <p>20 textbook on epidemiology, correct?</p> <p>21 MS. MILLER: Objection.</p> <p>22 THE WITNESS: I know of a</p> <p>23 textbook that he wrote. He may have</p> <p>24 written multiple, but I know of one.</p> <p>25</p>	<p style="text-align: right;">Page 69</p> <p>1 full-time professor at the Bloomberg School</p> <p>2 of Public Health, correct?</p> <p>3 A. It says right here that he's a</p> <p>4 full-time professor.</p> <p>5 Q. Have you spoke to Dr. Szklo?</p> <p>6 MS. MILLER: Objection.</p> <p>7 THE WITNESS: This Dr. Szklo?</p> <p>8 Yeah.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Szklo, is that how you</p> <p>11 pronounce it?</p> <p>12 A. I think so.</p> <p>13 Q. Okay.</p> <p>14 A. I'm not sure. Again, I know of</p> <p>15 him, and I don't think I've ever met him.</p> <p>16 Hopkins is a big place.</p> <p>17 Q. Now, I've -- it's also</p> <p>18 collaborative, right?</p> <p>19 A. It is.</p> <p>20 Q. You told me it's very</p> <p>21 collaborative.</p> <p>22 A. It is. But it's a very big</p> <p>23 place.</p> <p>24 Q. Understood.</p> <p>25 But that's a department that</p>

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<p style="text-align: right;">Page 70</p> <p>1 you've -- I mean, is there anything that</p> <p>2 would prevent you from speaking to Dr. Szklo?</p> <p>3 MS. MILLER: Objection.</p> <p>4 THE WITNESS: If I had a reason</p> <p>5 to. But there are many people on here</p> <p>6 that I actually have collaborated</p> <p>7 with, so --</p> <p>8 QUESTIONS BY MR. TISI:</p> <p>9 Q. Okay.</p> <p>10 A. In particular, Dr. Kirk right</p> <p>11 here, I think he's on many of my articles.</p> <p>12 So, you know, it just depends.</p> <p>13 If there was something specific</p> <p>14 that I thought that we could work on or I had</p> <p>15 a question, I'd just e-mail or call him right</p> <p>16 up and go over there.</p> <p>17 Q. Good to know. We'll talk about</p> <p>18 that.</p> <p>19 (Merlo Exhibit 7 marked for</p> <p>20 identification.)</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. I showed you Exhibit 4, which</p> <p>23 was your personal web page from Johns Hopkins</p> <p>24 pulmonary critical care department.</p> <p>25 Now let me show you the web</p>	<p style="text-align: right;">Page 72</p> <p>1 Do you see that?</p> <p>2 A. I do.</p> <p>3 Q. And if you click on that, on</p> <p>4 the computer, you get the second page of this</p> <p>5 document, which is a course catalog.</p> <p>6 Do you see that?</p> <p>7 A. I do.</p> <p>8 Q. And it says, "No results."</p> <p>9 A. Okay.</p> <p>10 Q. Okay. Do you teach any courses</p> <p>11 in epidemiology?</p> <p>12 A. I do. I teach two.</p> <p>13 Q. Which ones do you teach?</p> <p>14 A. I teach a course called the</p> <p>15 Science of Clinical Investigation and --</p> <p>16 Q. And what is -- I'm sorry.</p> <p>17 A. And that -- and the specific</p> <p>18 aspect of that is the design of clinical</p> <p>19 studies. We have both an in-person class and</p> <p>20 an online course.</p> <p>21 Q. Okay. And is any part of that</p> <p>22 course the discussion of the application of</p> <p>23 the Bradford Hill framework to answering a</p> <p>24 question of causation?</p> <p>25 MS. MILLER: Objection.</p>
<p style="text-align: right;">Page 71</p> <p>1 page from the Johns Hopkins department of</p> <p>2 epidemiology, which I'd like to have marked</p> <p>3 as Exhibit Number 7.</p> <p>4 Do you see that?</p> <p>5 A. I see a faculty directory for</p> <p>6 Johns Hopkins Bloomberg School of Public</p> <p>7 Health.</p> <p>8 Q. All right. And underneath it</p> <p>9 says, "department affiliation." It says,</p> <p>10 "school of medicine, primary" and</p> <p>11 "epidemiology, joint."</p> <p>12 Do you see that?</p> <p>13 A. I do.</p> <p>14 Q. What does it mean to be</p> <p>15 primary, and what does it mean to be joint?</p> <p>16 A. I actually have no idea. I</p> <p>17 know that my first appointment at Johns</p> <p>18 Hopkins was with the School of Medicine, and</p> <p>19 then because I was teaching courses over at</p> <p>20 the School of Public Health and collaborating</p> <p>21 with some of the investigators over there, we</p> <p>22 talked about another appointment, which I</p> <p>23 guess would be called a joint appointment.</p> <p>24 Q. Okay. It says here, "View</p> <p>25 current courses."</p>	<p style="text-align: right;">Page 73</p> <p>1 THE WITNESS: I don't know that</p> <p>2 I have a specific slide that would say</p> <p>3 Bradford -- there may be. I'd have to</p> <p>4 look back. But we certainly do talk</p> <p>5 about causality.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. And one of the things -- do you</p> <p>8 have slides that you use in that course?</p> <p>9 A. I have slides, and other</p> <p>10 instructors have slides.</p> <p>11 Q. Do you have any objection to</p> <p>12 producing it to us?</p> <p>13 MS. MILLER: I don't think</p> <p>14 that's his decision whether to object</p> <p>15 or not. I think that would be our</p> <p>16 objection.</p> <p>17 MR. TISI: I'm asking whether</p> <p>18 he has any objection.</p> <p>19 MS. MILLER: That's not an</p> <p>20 appropriate question for the witness.</p> <p>21 MR. TISI: I understand.</p> <p>22 Objection.</p> <p>23 MS. MILLER: But if it is</p> <p>24 appropriate or not --</p> <p>25 MR. TISI: Objection.</p>

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<p style="text-align: right;">Page 74</p> <p>1 Objection.</p> <p>2 MS. MILLER: No, I'm going to</p> <p>3 speak.</p> <p>4 MR. TISI: No, you're not.</p> <p>5 MS. MILLER: You're talking --</p> <p>6 Yes, I am.</p> <p>7 MR. TISI: No, you're not.</p> <p>8 MS. MILLER: Really? You want</p> <p>9 to watch?</p> <p>10 MR. TISI: Let's call the</p> <p>11 judge. Let's go off the record and</p> <p>12 call the judge.</p> <p>13 MS. MILLER: We're going to off</p> <p>14 the record and call the judge and tell</p> <p>15 her that you asked the witness if he</p> <p>16 has any objection to producing a</p> <p>17 document --</p> <p>18 MR. TISI: Yes, does he have</p> <p>19 personal --</p> <p>20 MS. MILLER: -- and won't let</p> <p>21 me talk about the objection. That is</p> <p>22 not an appropriate question.</p> <p>23 MR. TISI: Does he have -- does</p> <p>24 he have any -- do you have any</p> <p>25 objection --</p>	<p style="text-align: right;">Page 76</p> <p>1 talcum powder?</p> <p>2 A. No, although I think it would</p> <p>3 be a very fun exercise during that class.</p> <p>4 Q. Okay. When is the next time</p> <p>5 you give the class?</p> <p>6 A. We give the in-person version</p> <p>7 in the fall, and we give the online version</p> <p>8 usually in the wintertime.</p> <p>9 Q. Have you ever taught strategies</p> <p>10 for investigating the causes of cancer?</p> <p>11 A. Can you ask that again?</p> <p>12 MS. MILLER: Objection.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. Yes.</p> <p>15 Have you ever taught any</p> <p>16 strategies for investigating the causes of</p> <p>17 cancer?</p> <p>18 MS. MILLER: Same objection.</p> <p>19 THE WITNESS: So I would have</p> <p>20 to say that in certain -- now, for</p> <p>21 instance, in this -- in this</p> <p>22 investigation looking at malignancies</p> <p>23 after a transplant that we did, yeah,</p> <p>24 certainly we talked about aspects of</p> <p>25 how to evaluate the potential</p>
<p style="text-align: right;">Page 75</p> <p>1 MS. MILLER: That is not an</p> <p>2 appropriate question. I'm instructing</p> <p>3 you not to answer.</p> <p>4 THE WITNESS: You can take the</p> <p>5 course.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. I'd love to take the course,</p> <p>8 Doctor.</p> <p>9 A. Great.</p> <p>10 Q. I'd love to learn about the</p> <p>11 levels of evidence. But let's --</p> <p>12 MS. SHARKO: Should we agree?</p> <p>13 MS. MILLER: Yeah.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Let's -- we're going -- on a</p> <p>16 break, we're going to call the judge on that</p> <p>17 question.</p> <p>18 You said you taught a second</p> <p>19 course. What is the second course?</p> <p>20 A. So there's an online version</p> <p>21 and there's an in-person version, and</p> <p>22 sometimes they're a little bit different;</p> <p>23 sometimes they're the same.</p> <p>24 Q. Okay. In any of these courses</p> <p>25 have you ever discussed your opinions on</p>	<p style="text-align: right;">Page 77</p> <p>1 exposure/outcome relationship.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. What article is that, so I can</p> <p>4 look it up?</p> <p>5 A. I'm trying to find the number</p> <p>6 here. 65.</p> <p>7 Q. Thank you.</p> <p>8 What is the title of the</p> <p>9 article? I'm sorry.</p> <p>10 A. "Risk Factors for De Novo</p> <p>11 Malignancy Following Lung Transplantation."</p> <p>12 Q. Okay. Do you know whether or</p> <p>13 not ovarian cancer -- there's an association</p> <p>14 between lung transplantation and ovarian</p> <p>15 cancer?</p> <p>16 MS. MILLER: Objection.</p> <p>17 MS. SHARKO: Could you keep</p> <p>18 your voice up, please, Mr. Tisi?</p> <p>19 MR. TISI: Sure. You know, I'd</p> <p>20 have to -- that's the first time I've</p> <p>21 ever heard you say that.</p> <p>22 MS. SHARKO: I know. I'm --</p> <p>23 MR. TISI: Well, this witness</p> <p>24 is actually pretty good in answering</p> <p>25 questions, so I appreciate that so</p>

20 (Pages 74 to 77)

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<p style="text-align: right;">Page 78</p> <p>1 far.</p> <p>2 THE WITNESS: I would have to</p> <p>3 specifically look back at that</p> <p>4 article. I don't specifically recall.</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. Okay. Now, could you go to</p> <p>7 Appendice C of your report? Your report</p> <p>8 which I believe is Exhibit Number 3.</p> <p>9 It's the list of cases that you</p> <p>10 have testified to over the past four years.</p> <p>11 A. Okay.</p> <p>12 Q. And that's exhibit -- and</p> <p>13 that's Exhibit 3 -- and that's Exhibit 3,</p> <p>14 correct?</p> <p>15 A. Yes, correct.</p> <p>16 Q. I want to have -- I believe</p> <p>17 counsel provided us with a supplemental</p> <p>18 exhibit to that. I'll make it 3B because I</p> <p>19 think we have a 3.</p> <p>20 (Merlo Exhibit 3B marked for</p> <p>21 identification.)</p> <p>22 MS. MILLER: You're talking</p> <p>23 about the fact that we didn't know</p> <p>24 what court one of the cases was in or</p> <p>25 something.</p>	<p style="text-align: right;">Page 80</p> <p>1 Q. Okay. Are there times that</p> <p>2 you've consulted on legal cases but not been</p> <p>3 an expert?</p> <p>4 MS. MILLER: Objection.</p> <p>5 THE WITNESS: Well, being asked</p> <p>6 to consult on a case, I've been</p> <p>7 considered an expert. There have been</p> <p>8 cases that I've turned down because I</p> <p>9 felt like my opinion -- or I felt like</p> <p>10 there wasn't -- there wasn't something</p> <p>11 that I could support or there wasn't</p> <p>12 something that was -- something that I</p> <p>13 could provide an opinion about.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Could you give me an estimate,</p> <p>16 if you would -- I'll talk about your work on</p> <p>17 behalf of Johnson &amp; Johnson in this case, but</p> <p>18 putting that aside for a moment, on the legal</p> <p>19 matters in which you have been either</p> <p>20 identified as an expert or consulted,</p> <p>21 approximately how much have you made the past</p> <p>22 year, money?</p> <p>23 A. Well, first off, I would like</p> <p>24 to clarify that I'm not working on behalf of</p> <p>25 Johnson &amp; Johnson.</p>
<p style="text-align: right;">Page 79</p> <p>1 MR. TISI: Honestly, I don't</p> <p>2 know. I don't have any idea.</p> <p>3 MS. MILLER: He's talking about</p> <p>4 this.</p> <p>5 MR. TISI: Okay. This is just</p> <p>6 a clerical thing, Doctor.</p> <p>7 Here's -- provided to us. It</p> <p>8 was a supplement. I'm not even going</p> <p>9 to spend any time with it. It's just</p> <p>10 a housekeeping thing.</p> <p>11 MS. MILLER: Yeah, I don't</p> <p>12 think Dr. Merlo was involved in that.</p> <p>13 MR. TISI: Okay.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Okay. So you've given</p> <p>16 testimony in the past four years 20 times?</p> <p>17 A. That seems about -- I mean, I</p> <p>18 don't know if it's exactly 20, but --</p> <p>19 whatever --</p> <p>20 Q. Well, I've counted them up.</p> <p>21 Five times in 2015; three times in 2016; five</p> <p>22 times in 2017, six times in 2018.</p> <p>23 Does that -- does that look</p> <p>24 about right to you?</p> <p>25 A. It looks about right.</p>	<p style="text-align: right;">Page 81</p> <p>1 And I would have to look at my</p> <p>2 tax statement because I don't recall.</p> <p>3 Q. Was it more than \$10,000?</p> <p>4 A. Probably.</p> <p>5 Q. More than 20?</p> <p>6 A. Probably.</p> <p>7 Q. More than 30?</p> <p>8 A. Probably was more than 30.</p> <p>9 Q. More than 40?</p> <p>10 A. Probably.</p> <p>11 Q. More than 50?</p> <p>12 A. Probably.</p> <p>13 Q. More than 60?</p> <p>14 A. In the last year, probably,</p> <p>15 yes.</p> <p>16 Q. More than 70?</p> <p>17 A. Maybe.</p> <p>18 Q. Okay. What about the year</p> <p>19 prior?</p> <p>20 A. I don't recall.</p> <p>21 Q. Okay. The prior -- last year</p> <p>22 you had six times in 2018. 2017 you had five</p> <p>23 times.</p> <p>24 Would it be approximately the</p> <p>25 same?</p>

21 (Pages 78 to 81)



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<p>1 MS. MILLER: Objection. He 2 said he doesn't remember. 3 MR. TISI: I can -- I can ask 4 these questions. 5 THE WITNESS: Again, I'd 6 probably have to look at my tax 7 records. I'd be just guessing. 8 QUESTIONS BY MR. TISI: 9 Q. Would it be more than 10? 10 A. I'd be guessing. 11 Q. Okay. Over the past four 12 years, have you been provided -- have you 13 provided expert work in litigation fairly 14 consistently? Is that something that you do? 15 MS. MILLER: Objection. 16 THE WITNESS: It's not 17 something I keep track of. I have 18 been -- I have offered opinions as an 19 expert witness, but I don't keep track 20 of how much or how little. 21 QUESTIONS BY MR. TISI: 22 Q. Now in this case, in 2019, have 23 you -- in 2019, have you given any 24 depositions -- we're now in April. Have you 25 been identified as an expert or given any</p>	<p>1 A. I see that, yes. 2 Q. Is that accurate? 3 A. This is an invoice. I haven't 4 seen it yet, but -- 5 Q. Did you do any work for 6 Johnson &amp; Johnson before December of 2018? 7 A. Again, I just would like to 8 clarify. I'm not working for Johnson &amp; 9 Johnson. 10 Q. Okay. Have you been paid by 11 Johnson &amp; Johnson for your time prior to 12 December of 2018? 13 A. Not that I recall. 14 Q. Okay. 15 MS. MILLER: Let us know when 16 it's a good time for a break. 17 QUESTIONS BY MR. TISI: 18 Q. The next document is an invoice 19 showing that you made an additional \$28,995 20 through April 7, 2019; is that correct? 21 MS. MILLER: I'm sorry? 22 THE WITNESS: I'm sorry, could 23 you ask that one more time? 24 MR. TISI: I'm sorry. I'm 25 sorry.</p>
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<p>1 opinions in 2019 other than in this case? 2 A. I'd have to look back through 3 my records. I don't remember. 4 Q. You don't remember giving any 5 depositions or signing any reports over the 6 past three, four months? 7 A. Again, I'd have to look at my 8 records. 9 Q. Okay. In this case we have 10 your records, which I'll mark in a minute. 11 Actually, I'll do it right now. Exhibit 12 Number 8, which are the records of -- 13 provided to us. 14 (Merlo Exhibit 8 marked for 15 identification.) 16 QUESTIONS BY MR. TISI: 17 Q. And it shows that you have made 18 in the Johnson &amp; Johnson litigation about 19 \$150,000 so far this year? 20 A. This looks like a bill or an 21 invoice. 22 Q. One is dated -- one is dated 23 March 1, 2019, and it's -- first date is 24 December 3, 2018, through March 17th, and 25 it's for \$116,000?</p>	<p>1 QUESTIONS BY MR. TISI: 2 Q. It shows just \$5 short of 30 -- 3 \$29,000 as of March 7, 2019? 4 A. That's what the invoice shows, 5 yes. 6 Q. It has a company or LLC here 7 called VeraMedica. 8 What is VeraMedica? 9 A. VeraMedica is an organization. 10 I'm not sure about the -- any of the 11 specifics there, but it's an organization 12 that I used for administrative purposes to 13 put binders together, to make photocopies, to 14 make -- to schedule meetings, those sort of 15 things. 16 Q. Are they a scientific 17 consulting company? 18 A. I have no idea. 19 Q. Do they provide -- did they 20 provide you any support for the reports that 21 you prepare -- the report you prepared in 22 this case? 23 A. Other than making a photocopy 24 or scheduling meetings or helping to give me 25 kind of an office away from an office, that's</p>



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<p style="text-align: right;">Page 86</p> <p>1 the support that they give me.</p> <p>2 Q. And if you give me about five,</p> <p>3 ten minutes, I think we can finish this.</p> <p>4 MR. TISI: Is that okay with</p> <p>5 you, Counsel?</p> <p>6 MS. MILLER: Sure.</p> <p>7 MR. TISI: Okay.</p> <p>8 QUESTIONS BY MR. TISI:</p> <p>9 Q. Your expert work you charge</p> <p>10 \$530 an hour, and \$720 an hour for your</p> <p>11 testimony?</p> <p>12 A. That's correct.</p> <p>13 Q. Okay. Those are -- those are</p> <p>14 numbers that are -- is there anything built</p> <p>15 into that number?</p> <p>16 We had Dr. Diette the other day</p> <p>17 where a certain portion of his bill went to</p> <p>18 somebody other than himself, so I'm asking</p> <p>19 you that question.</p> <p>20 A. You know, and I'd have -- I</p> <p>21 don't actually know, but I'd have to look</p> <p>22 back or I'd have to talk -- the</p> <p>23 administrative services for -- that were</p> <p>24 supported to me by VeraMedica may be built</p> <p>25 into that.</p>	<p style="text-align: right;">Page 88</p> <p>1 Q. Well, let me show you -- and</p> <p>2 I'm taking this out of order a little bit.</p> <p>3 There's a website that I go to sometimes to</p> <p>4 find this information out.</p> <p>5 It identifies -- and I'm going</p> <p>6 to show you...</p> <p>7 MS. MILLER: We're up to what</p> <p>8 number exhibit?</p> <p>9 MR. TISI: This is 47. It's</p> <p>10 taken out of order because everything</p> <p>11 is marked.</p> <p>12 (Merlo Exhibit 47 marked for</p> <p>13 identification.)</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. It lists payments made by</p> <p>16 pharmaceutical companies to doctors, and I'm</p> <p>17 just curious as to whether this is accurate</p> <p>18 or not.</p> <p>19 Were you paid approximately</p> <p>20 \$44,000 in 2016 --</p> <p>21 MS. MILLER: Objection.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. -- by --</p> <p>24 MS. MILLER: Sorry, I thought</p> <p>25 you were done.</p>
<p style="text-align: right;">Page 87</p> <p>1 MS. MILLER: I would note that</p> <p>2 the -- it says 540 on the --</p> <p>3 MR. TISI: Okay.</p> <p>4 MS. MILLER: -- on here and it</p> <p>5 says 530 on here, so...</p> <p>6 THE WITNESS: And again, I'm</p> <p>7 not sure of the specifics.</p> <p>8 QUESTIONS BY MR. TISI:</p> <p>9 Q. Okay. Now, in addition to</p> <p>10 consulting for litigation purposes like you</p> <p>11 are here, have you also worked directly for</p> <p>12 pharmaceutical companies over the past four,</p> <p>13 five years?</p> <p>14 A. I have not worked directly for</p> <p>15 pharmaceutical companies --</p> <p>16 Q. Well, I'm sorry.</p> <p>17 A. -- over the past four or five</p> <p>18 years.</p> <p>19 Q. That's a bad question.</p> <p>20 Have you been provided funding</p> <p>21 by pharmaceuticals companies like Novartis,</p> <p>22 for example?</p> <p>23 A. So it depends. And that's a</p> <p>24 very general question, so you'd have to be</p> <p>25 very -- even more specific about that.</p>	<p style="text-align: right;">Page 89</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. -- by, among others, Novartis?</p> <p>3 MS. MILLER: Objection.</p> <p>4 THE WITNESS: So I'm not really</p> <p>5 sure what this website is.</p> <p>6 I do -- I have been involved in</p> <p>7 think tanks for -- involving other</p> <p>8 doctors and folks to talk about</p> <p>9 aspects of disease, and there have</p> <p>10 been honorariums involved with that.</p> <p>11 I also give speeches to groups,</p> <p>12 mainly groups of doctors and nurses</p> <p>13 and teams that take care of patients</p> <p>14 with cystic fibrosis. And those</p> <p>15 speeches are sometimes sponsored by</p> <p>16 pharmaceutical companies, so -- and</p> <p>17 I'm provided an honorarium to give</p> <p>18 that.</p> <p>19 So this doesn't surprise me.</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. Okay. So -- and that's what</p> <p>22 I'm trying to get at here, Doctor.</p> <p>23 You can call them honorarium.</p> <p>24 You can call them whatever you want. You</p> <p>25 get -- you get a check from the</p>

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<p style="text-align: right;">Page 90</p> <p>1 pharmaceutical companies for outside -- work 2 outside of your official duties at Johns 3 Hopkins. 4 And this goes from 2013 to 5 2016, correct? 6 MR. LOCKE: Objection. 7 THE WITNESS: And I am going to 8 say that they're honorarium because 9 that's what they're called. 10 QUESTIONS BY MR. TISI: 11 Q. Okay. 12 A. And I'm asked by sometimes 13 other centers to come, and that -- and 14 that -- to give a speech or a talk to the 15 group, and that talk or speech might be 16 sponsored by a pharmaceutical industry, and 17 that's what this reflects. 18 Q. Okay. And so without getting 19 down to the minutiae, this has 44,000, 20 approximately, in 2016, 31,000 in 2015, 21 79,000 in 2014, and 42,000, approximately, 22 more or less, in 2013. 23 Is that about -- is that 24 accurate or in that ballpark? 25 A. I mean, I'd have to look</p>	<p style="text-align: right;">Page 92</p> <p>1 a group that's taking care of patients with 2 advanced lung disease due to cystic fibrosis. 3 And most times the talks are a 4 description about the disease, either to 5 educate the teams or describe how the process 6 of when a kid grows up to be an adult with 7 cystic fibrosis, how do you take care of the 8 transition process. 9 Most of them don't involve a 10 specific therapy for cystic fibrosis. 11 Oftentimes specific therapies are talked 12 about after the talk with the group, but most 13 times it's done for education purposes. 14 Q. But most of the companies that 15 pay these honorariums actually do produce 16 products used to treat cystic fibrosis and 17 pulmonary disease, correct? 18 A. Which companies are you 19 referring to? 20 Q. Gilead, Novartis. 21 A. Gilead, Novartis do have -- 22 well, Novartis not anymore, but -- 23 Q. They did at the time? 24 A. -- Gilead and Novartis did have 25 products that were used to treat patients</p>
<p style="text-align: right;">Page 91</p> <p>1 through my records, but that's what the 2 website says. 3 Q. Okay. And is that money that 4 you get as an honorarium yours? 5 A. It is mine, yes. 6 Q. And did you do it in 2017, 7 2018, and continue into 2019? 8 MS. MILLER: Objection. Vague. 9 THE WITNESS: I'd have to look 10 through my records. I have done -- 11 I've given much less talks in the last 12 few years. 13 QUESTIONS BY MR. TISI: 14 Q. And on all the products that 15 you speak about or all the companies that 16 you -- they -- would it be fair to say that 17 they are all focused in the pulmonary area; 18 in other words, either involved treatments 19 for pulmonary disease or descriptions of 20 pulmonary disease? Correct? 21 A. So there's a lot to that 22 question because you mentioned products, you 23 mentioned descriptions, and I probably should 24 break it down a little bit. 25 The talks are usually given to</p>	<p style="text-align: right;">Page 93</p> <p>1 with cystic fibrosis. 2 Q. Okay. So just to wrap this up, 3 and I -- we'll move on to the next topic and 4 take our break. 5 MS. MILLER: Take our break. 6 QUESTIONS BY MR. TISI: 7 Q. You have done work in 8 litigation, which we've talked about earlier, 9 and you did speeches and talks for which you 10 received honorarium from pharmaceutical 11 companies. 12 Do you also -- have you also 13 provided consulting services to 14 pharmaceutical companies or the like that are 15 not giving speeches and all that? 16 A. I mean, I've helped design some 17 of these talks, put together the slides for 18 them, and I have been provided honorariums 19 for that as well. 20 MR. TISI: Let's take our 21 break. 22 VIDEOGRAPHER: The time is 23 10:23 a.m., and we're going off the 24 record. 25 (Off the record at 10:23 a.m.)</p>

24 (Pages 90 to 93)

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<p style="text-align: right;">Page 94</p> <p>1 VIDEOGRAPHER: The time is</p> <p>2 10:42 a.m., and we are back on the</p> <p>3 record.</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. Just a couple of questions real</p> <p>6 briefly before I move on to your report.</p> <p>7 You received your master's in</p> <p>8 public health from Johns Hopkins School of</p> <p>9 Public Health in 2003?</p> <p>10 A. Yes, I believe so.</p> <p>11 Q. And who was your advisor?</p> <p>12 A. My advisor in the School of</p> <p>13 Public Health, or the School of Medicine at</p> <p>14 that time?</p> <p>15 Q. School of Public Health.</p> <p>16 A. I believe my advisor may have</p> <p>17 been Marie Diener Smith, but I don't</p> <p>18 specifically recall.</p> <p>19 Q. Did you do a Capstone?</p> <p>20 A. At the time the Capstone</p> <p>21 project was not part of the master's in</p> <p>22 public health.</p> <p>23 Q. Okay. Did you have to do any</p> <p>24 kind of final project to get your MPH?</p> <p>25 A. We had a final project</p>	<p style="text-align: right;">Page 96</p> <p>1 A. I don't know specifically. I</p> <p>2 don't know if advisors are assigned or</p> <p>3 advisors are recommended and then the student</p> <p>4 decides. I just don't know.</p> <p>5 Q. Have you ever had a student who</p> <p>6 did a Capstone project with you that was not</p> <p>7 pulmonary in nature?</p> <p>8 A. I've had students who have</p> <p>9 worked with me that have been outside of</p> <p>10 pulmonary and critical care medicine.</p> <p>11 Q. Okay.</p> <p>12 A. Two have been surgeons who have</p> <p>13 worked on -- that we wound up working on many</p> <p>14 projects together.</p> <p>15 Q. Okay. All right. So when was</p> <p>16 the first time you met with -- who was your</p> <p>17 primary contact for the ovarian cancer report</p> <p>18 that we've marked as Exhibit 3? Which of the</p> <p>19 lawyers?</p> <p>20 Who first contacted you for</p> <p>21 this project?</p> <p>22 A. Ms. Miller.</p> <p>23 Q. Okay. And when was that done?</p> <p>24 When was the first contact you had with</p> <p>25 Ms. Miller?</p>
<p style="text-align: right;">Page 95</p> <p>1 assignment with Biostatistics IV where we had</p> <p>2 to design a clinical study, do the analysis</p> <p>3 and write up a manuscript, which was</p> <p>4 eventually published, but that was my final</p> <p>5 project.</p> <p>6 Q. And was it a pulmonary study?</p> <p>7 A. It was a study looking at risk</p> <p>8 factors for resistant organisms in cystic</p> <p>9 fibrosis.</p> <p>10 Q. Okay. So it was a pulmonary</p> <p>11 cystic fibrosis study?</p> <p>12 A. It was a cystic fibrosis study.</p> <p>13 Q. Okay.</p> <p>14 A. An epidemiologic cystic</p> <p>15 fibrosis study.</p> <p>16 Q. Are you a Capstone advisor for</p> <p>17 any students in the School of Public Health?</p> <p>18 A. I have been in the past. I'm</p> <p>19 not this year.</p> <p>20 Q. Okay. How does the School of</p> <p>21 Public Health assign students to advisors for</p> <p>22 their Capstone project?</p> <p>23 I mean, do they look at</p> <p>24 qualifications, et cetera, areas of interest,</p> <p>25 research?</p>	<p style="text-align: right;">Page 97</p> <p>1 A. 2018.</p> <p>2 Q. Okay. When?</p> <p>3 A. Late 2018. I don't</p> <p>4 specifically recall.</p> <p>5 Q. The first billing record that</p> <p>6 we had when we looked at that exhibit, I</p> <p>7 think Exhibit 8, had a December 2018 date.</p> <p>8 Is that about right?</p> <p>9 A. It would have been before that.</p> <p>10 Q. Okay. Was December 2018 the</p> <p>11 first actual work you did on the project?</p> <p>12 A. What do you mean by "work"?</p> <p>13 Q. It's the first time you billed,</p> <p>14 so why would that be the -- I mean, did you</p> <p>15 do work for which you did not bill?</p> <p>16 A. It -- just if you could be a</p> <p>17 little bit more specific about what you mean</p> <p>18 by "work."</p> <p>19 Q. I can't go by anything any --</p> <p>20 for more than what you billed.</p> <p>21 How long between the first</p> <p>22 contact and the first work you did on the</p> <p>23 case that would start the process of</p> <p>24 resulting in the report that was issued in</p> <p>25 February?</p>

25 (Pages 94 to 97)

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<p>1 MS. MILLER: Objection.</p> <p>2 THE WITNESS: I don't</p> <p>3 specifically recall.</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. Okay.</p> <p>6 MS. MILLER: Don't forget to</p> <p>7 give me ten seconds before you answer.</p> <p>8 THE WITNESS: I'm sorry.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Prior to -- now, we had</p> <p>11 indicated that you did some litigation work.</p> <p>12 You did some consulting work for which you</p> <p>13 received honoraria.</p> <p>14 Had you ever worked -- had you</p> <p>15 ever had -- done litigation work for</p> <p>16 Johnson &amp; Johnson previously?</p> <p>17 A. Well, again, I'd have to</p> <p>18 clarify. I'm not doing litigation work for</p> <p>19 Johnson &amp; Johnson.</p> <p>20 Q. How would you -- so we don't</p> <p>21 have to dance around that issue, how would</p> <p>22 you --</p> <p>23 A. But you keep asking it, so --</p> <p>24 MR. LOCKE: Objection.</p> <p>25</p>	<p>1 me, right?</p> <p>2 So you're being paid by the</p> <p>3 folks sitting next to you, and where it comes</p> <p>4 from, we'll leave that -- we'll leave that to</p> <p>5 other people to decide.</p> <p>6 The question is: You are being</p> <p>7 paid to be here today?</p> <p>8 A. I will submit a bill, and I</p> <p>9 will be paid for being here today.</p> <p>10 Q. Have you ever had any similar</p> <p>11 circumstances in cases involving Johnson &amp;</p> <p>12 Johnson before?</p> <p>13 A. I don't believe that I have --</p> <p>14 I don't believe so.</p> <p>15 Q. Okay. Has Johnson &amp; Johnson,</p> <p>16 putting litigation aside, ever hired you or</p> <p>17 paid you honoraria to actually speak on a</p> <p>18 topic?</p> <p>19 A. I've never been paid an</p> <p>20 honorarium or have been hired by Johnson &amp;</p> <p>21 Johnson.</p> <p>22 Q. Okay. Have they ever consulted</p> <p>23 you in any way for any scientific reason</p> <p>24 outside of litigation?</p> <p>25 A. Johnson &amp; Johnson has not</p>
Page 99	Page 101
<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. Well, okay. So you tell me --</p> <p>3 you tell me how I would phrase it so we don't</p> <p>4 have to keep going back and forth on that.</p> <p>5 MS. MILLER: Objection.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. What makes you more</p> <p>8 comfortable?</p> <p>9 Have you ever done consulting</p> <p>10 work for Johnson &amp; Johnson in a litigation</p> <p>11 context before?</p> <p>12 A. Again, the premise there is</p> <p>13 that I'm doing something for someone, and I'm</p> <p>14 not doing something for anyone.</p> <p>15 Q. Are you being paid by them?</p> <p>16 A. I don't know who I'm being paid</p> <p>17 by.</p> <p>18 Q. You don't know who -- you don't</p> <p>19 know that the lawyers here are paying you for</p> <p>20 your time here today?</p> <p>21 A. Again, I don't know who is</p> <p>22 paying me. I know I'm getting paid, but I</p> <p>23 don't know who is paying me.</p> <p>24 Q. Okay. You're being paid in</p> <p>25 this litigation. You're not being paid by</p>	<p>1 consulted me outside of this litigation.</p> <p>2 Q. Now, Merlo -- you know that</p> <p>3 this report was filed in the context of</p> <p>4 litigation, correct, Exhibit 3? It's got a</p> <p>5 legal caption on it.</p> <p>6 A. Exhibit 3, yes.</p> <p>7 Q. Okay. And it was requested as</p> <p>8 a result -- it was -- I'm sorry, it was</p> <p>9 generated as a result of a request from the</p> <p>10 lawyers for J&amp;J?</p> <p>11 A. I was asked -- I'll just read</p> <p>12 this right here. I was asked to address</p> <p>13 fundamental tenets of epidemiology, to review</p> <p>14 epidemiology related to the potential</p> <p>15 association between perineal talc use and</p> <p>16 ovarian cancer, to review plaintiffs'</p> <p>17 epidemiologic expert reports, and to offer my</p> <p>18 opinions on their methodologies.</p> <p>19 Q. Who asked you to do that?</p> <p>20 A. I was asked by Ms. Miller.</p> <p>21 Q. Okay. And when you drafted --</p> <p>22 when you did that, you understood that your</p> <p>23 report was being submitted in the context of</p> <p>24 this litigation, correct?</p> <p>25 A. I understood that I would put</p>

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<p style="text-align: right;">Page 102</p> <p>1 together a report and that would likely be 2 submitted. 3 Q. In litigation? 4 A. In litigation. 5 Q. Okay. So this report that you 6 have in front of you, Exhibit Number 6, was 7 not generated in your normal course of your 8 professional work as a professor or -- excuse 9 me, as an assistant professor at Johns 10 Hopkins, either in the School of Public 11 Health or the department of medicine? 12 MS. MILLER: Objection. 13 THE WITNESS: Can you ask that 14 again? 15 QUESTIONS BY MR. TISI: 16 Q. Yes. 17 So the report that you have in 18 front of you, Exhibit Number 3, was 19 generated -- was not generated in the normal 20 course of your professional work as a 21 professor or researcher at either the School 22 of Medicine or the School of Public Health at 23 Johns Hopkins? 24 MS. MILLER: Objection. 25 THE WITNESS: So I'd say it</p>	<p style="text-align: right;">Page 104</p> <p>1 THE WITNESS: Can you ask that 2 again? 3 QUESTIONS BY MR. TISI: 4 Q. Yes. 5 Would you have done this report 6 had Ms. Miller not asked you to do it? 7 A. I would not have specifically 8 put this together. 9 Q. Okay. 10 A. Had not been asked to provide 11 my opinions on this topic. 12 Q. Right. 13 And before Ms. Miller reached 14 out to you in December of 2018, some five 15 months ago, you had never expressed an 16 opinion one way or another about the risk of 17 ovarian cancer associated with talcum powder 18 products, have you? 19 MR. LOCKE: Objection. 20 MS. MILLER: Objection. 21 THE WITNESS: Can you ask that 22 one more time? 23 QUESTIONS BY MR. TISI: 24 Q. Yes. 25 A. I'm sorry, I'm just getting --</p>
<p style="text-align: right;">Page 103</p> <p>1 depends. Because if we look at it as 2 a report in itself and how I approach 3 this subject, that would be very 4 similar to how I approach a lot of 5 things in my -- in my career. So -- 6 and in my professional duties within 7 the School of Medicine and 8 epidemiology. 9 So is this any different? No. 10 QUESTIONS BY MR. TISI: 11 Q. I didn't ask you that question, 12 Doctor. With all due respect, I think you 13 need to listen to my question. 14 My question is: Was this 15 particular report on talcum powder product 16 and ovarian cancer done in connection with 17 your duties and responsibilities at Johns 18 Hopkins? 19 MS. MILLER: That wasn't your 20 question. 21 MR. LOCKE: Objection. 22 MS. MILLER: That's a different 23 question. I just want to make that 24 clear. And I'm objecting to this 25 question as well.</p>	<p style="text-align: right;">Page 105</p> <p>1 when I hear objections, I just -- 2 Q. Yeah, they're intended to be 3 that way. 4 A. No, but it's -- so I need to 5 think about the question. 6 MS. MILLER: They're not 7 intended to be that way. That was not 8 a necessary comment. 9 QUESTIONS BY MR. TISI: 10 Q. Let me ask you this question. 11 Before your report in February, 12 Exhibit Number 3, had you ever expressed the 13 opinion on page 46 of your report that says, 14 "When analyzed in a methodologic manner, the 15 body of medical literature simply does not 16 support the conclusion that perineal exposure 17 to talc causes ovarian cancer"? 18 Have you ever said that 19 statement or any statement similar to that 20 prior to your report being filed on 21 February 25, 2019? 22 A. I had not said that prior to 23 this because I had not reviewed all of this 24 literature prior to that. 25 Q. Okay. So all the literature</p>

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<p style="text-align: right;">Page 106</p> <p>1 review that you did in this case was as a</p> <p>2 result of being retained in this case?</p> <p>3 A. The literature review that I</p> <p>4 did in this case was because I was asked to</p> <p>5 provide an opinion on that.</p> <p>6 Q. Prior to Ms. Miller contacting</p> <p>7 you, had you ever read any of the articles</p> <p>8 that you read in connection with this report</p> <p>9 on talc and ovarian cancer?</p> <p>10 A. Likely no.</p> <p>11 Q. Okay. Now, you mentioned, if</p> <p>12 you go to page 1 of your report, the scope of</p> <p>13 your report -- as I count it, you have -- you</p> <p>14 did three things.</p> <p>15 You were asked to address</p> <p>16 fundamental tenets of epidemiology, correct?</p> <p>17 A. Address fundamental tenets of</p> <p>18 epidemiology.</p> <p>19 Q. Okay. Number 2, review the</p> <p>20 epidemiology of the potential association</p> <p>21 between perineal talc use and ovarian cancer,</p> <p>22 correct?</p> <p>23 A. To review the epidemiology</p> <p>24 related to the potential association between</p> <p>25 perineal talc use and ovarian cancer,</p>	<p style="text-align: right;">Page 108</p> <p>1 MS. MILLER: I think if you let</p> <p>2 him finish --</p> <p>3 MR. TISI: I said I'm</p> <p>4 withdrawing the question. Okay?</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. I assume that you have reviewed</p> <p>7 fundamental tenets of epidemiology prior to</p> <p>8 December of 2018?</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: I have reviewed</p> <p>11 and I teach fundamental tenets of</p> <p>12 epidemiology.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. Okay. Putting that aside,</p> <p>15 prior to December of 2018, have you ever</p> <p>16 reviewed the epidemiology related to the</p> <p>17 potential exposure between perineal talc use</p> <p>18 and ovarian cancer?</p> <p>19 A. The potential exposure?</p> <p>20 Q. Association.</p> <p>21 A. I had not reviewed epidemiology</p> <p>22 related to the potential association between</p> <p>23 perineal talc and ovarian cancer.</p> <p>24 Q. Before December of 2018?</p> <p>25 A. Specifically, it may have been</p>
<p style="text-align: right;">Page 107</p> <p>1 correct.</p> <p>2 Q. And the third assignment was to</p> <p>3 review plaintiffs' epidemiology reports and</p> <p>4 offer your opinion on their methodologies?</p> <p>5 A. So those are two different</p> <p>6 things. To review plaintiffs' epidemiology</p> <p>7 expert reports and then to offer my opinions</p> <p>8 on their methodologies would be a separate</p> <p>9 thing.</p> <p>10 Q. Okay. All right. And to be</p> <p>11 clear, the scope -- the things that you did</p> <p>12 for this report as indicated on page 1, the</p> <p>13 four items we've talked about, are things you</p> <p>14 never did before December of 2019 {sic}?</p> <p>15 MS. MILLER: Objection.</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. 2018?</p> <p>18 MS. MILLER: Objection.</p> <p>19 THE WITNESS: Well, not</p> <p>20 necessarily.</p> <p>21 I think if we --</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Actually, let me rephrase the</p> <p>24 question.</p> <p>25 You have --</p>	<p style="text-align: right;">Page 109</p> <p>1 November. I don't remember when we first</p> <p>2 talked, but --</p> <p>3 Q. Let's say the last quarter.</p> <p>4 A. -- late 2018.</p> <p>5 Q. Okay. So within the past eight</p> <p>6 or nine months?</p> <p>7 A. Before late 2018? No, I did --</p> <p>8 had not reviewed the epidemiology --</p> <p>9 Q. Okay.</p> <p>10 A. -- related to the potential</p> <p>11 association between perineal talc exposure</p> <p>12 and ovarian cancer.</p> <p>13 Q. Okay. And if you go to</p> <p>14 page 46 -- and we touched on this. You said</p> <p>15 your opinion on Issue Number 2, which would</p> <p>16 be the results of your analysis of the</p> <p>17 epidemiology related to the potential</p> <p>18 association between perineal use and ovarian</p> <p>19 cancer, your opinion was: When analyzed in a</p> <p>20 methodologic manner, the body of medical</p> <p>21 literature simply does not support the</p> <p>22 conclusion that perineal talc exposure causes</p> <p>23 ovarian cancer.</p> <p>24 A. And we're referring to page 46</p> <p>25 of --</p>



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<p>1 Q. Correct.</p> <p>2 A. -- this report?</p> <p>3 And which line was that?</p> <p>4 Q. The last paragraph.</p> <p>5 A. "When analyzed in a</p> <p>6 methodologic manner, the body of medical</p> <p>7 literature simply does not support the</p> <p>8 conclusion that perineal exposure to talc</p> <p>9 causes ovarian cancer," yes.</p> <p>10 (Merlo Exhibit 9 marked for</p> <p>11 identification.)</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. And I have that conclusion</p> <p>14 marked as Exhibit Number 9. Read it and tell</p> <p>15 me if it's correct.</p> <p>16 A. That's correct.</p> <p>17 Q. And that's your professional</p> <p>18 opinion on the issue of causation, correct?</p> <p>19 A. That is my professional and</p> <p>20 epidemiologic opinion on causation.</p> <p>21 Q. Okay.</p> <p>22 A. Correct.</p> <p>23 Q. Did you -- in addition to</p> <p>24 providing basic epidemiologic principles, did</p> <p>25 you apply your professional and epidemiologic</p>	<p>1 a group of epidemiology studies mean, true?</p> <p>2 A. Can you say that again?</p> <p>3 Q. Yeah.</p> <p>4 Oftentimes experts in</p> <p>5 epidemiology disagree about what an</p> <p>6 epidemiology study actually means or a group</p> <p>7 of epidemiology studies actually means?</p> <p>8 A. There may be instances where</p> <p>9 epidemiologists may disagree on methodologies</p> <p>10 and how a study was performed.</p> <p>11 The interpretation of results</p> <p>12 is usually something that is not disagreed</p> <p>13 upon. It's usually the methodology that</p> <p>14 leads to the disagreement.</p> <p>15 Q. Well, for an individual study,</p> <p>16 the results are what the results are, true?</p> <p>17 A. For an individual study, the</p> <p>18 results are usually what the results are</p> <p>19 based on -- but those are -- with the caveat</p> <p>20 that there are a lot of aspects that go into</p> <p>21 those results: the study design, the study</p> <p>22 type, whether or not bias and confounding was</p> <p>23 accounted for before or after the analysis,</p> <p>24 was the analysis appropriate.</p> <p>25 So those results can't just be</p>
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<p>1 judgment to answer that question?</p> <p>2 A. I don't know what you mean by</p> <p>3 "epidemiologic judgment."</p> <p>4 Q. Well, this -- epidemiology</p> <p>5 isn't the kind science where you just plug</p> <p>6 numbers in and you come out with an answer,</p> <p>7 right?</p> <p>8 MS. MILLER: Objection.</p> <p>9 THE WITNESS: Well,</p> <p>10 epidemiology can be very objective and</p> <p>11 not subjective, and oftentimes there</p> <p>12 are numbers involved in epidemiology.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. Clearly there are numbers --</p> <p>15 clearly there are numbers involved.</p> <p>16 But an expert in epidemiology</p> <p>17 also has to use their professional judgment</p> <p>18 interpreting the numbers, correct?</p> <p>19 MS. MILLER: Objection.</p> <p>20 THE WITNESS: I don't know what</p> <p>21 you mean by "interpreting the</p> <p>22 numbers."</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. Well, oftentimes experts</p> <p>25 disagree about what an epidemiology study or</p>	<p>1 taken out of context without looking at all</p> <p>2 the other aspects of the study.</p> <p>3 Q. Okay. And when -- now, putting</p> <p>4 aside looking at the results of an individual</p> <p>5 study, when you're looking at a body of</p> <p>6 literature, all right, multiple epidemiology</p> <p>7 studies, multiple biologic studies, and</p> <p>8 trying to interpret a body of literature, do</p> <p>9 you use professional judgment?</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: Again, I don't --</p> <p>12 I don't know what "professional</p> <p>13 judgment" means. I don't understand</p> <p>14 what you mean by that, so --</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. Do you know if that's a phrase</p> <p>17 that's used in textbooks that are used at</p> <p>18 Johns Hopkins, that you teach students?</p> <p>19 MS. MILLER: Objection.</p> <p>20 THE WITNESS: I mean, I have no</p> <p>21 idea. There's lots of textbooks. You</p> <p>22 would have to point me to one that</p> <p>23 you're referring to.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. We will do that.</p>

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<p style="text-align: right;">Page 114</p> <p>1 Now, apart from your own 2 causation opinion, which we've marked as 3 Exhibit Number 9, I think, right there -- is 4 that number 9? 5 A. That's number 9. 6 Q. You also, as part of your 7 assignment, offered opinions on the 8 plaintiffs' experts' reports, true? 9 A. That's correct. 10 Q. Okay. And in fact, if you go 11 to page 46 of your report, you devoted the 12 vast majority of your conclusion paragraphs 13 to discussing the methodologies that are used 14 by plaintiffs' experts in reaching their 15 conclusions. 16 Do you see that? 17 A. Yes. 18 Q. Okay. For example, you say in 19 paragraph 2, "The methodologies used by 20 plaintiffs' experts ignore fundamental 21 principles of epidemiology. In particular, 22 plaintiffs' experts ignore the hierarchy of 23 evidence evaluating studies and rely on study 24 designs that are inherently susceptible to 25 bias. Specifically plaintiffs' experts pay</p>	<p style="text-align: right;">Page 116</p> <p>1 THE WITNESS: So in -- 2 MS. MILLER: Ten seconds. 3 THE WITNESS: So in general, 4 the hierarchy of evidence does put 5 certain study designs above others. 6 Meta-analyses are usually put above 7 randomized controlled trials. 8 Randomized controlled trials are 9 usually put above cohort studies. 10 Cohort studies are usually put above 11 case-control studies. Case-control 12 studies are usually put above case 13 series or cross-sectional studies. 14 But it depends. It depends on 15 many, many -- it depends on many, many 16 factors, and you can't just take that 17 in itself. 18 A poorly designed randomized 19 controlled trial may be much less 20 informative than a very, very good 21 cohort study. 22 QUESTIONS BY MR. TISI: 23 Q. Okay. Then you say -- a 24 separate criticism. You say, "Plaintiffs' 25 experts generally agree that even if the</p>
<p style="text-align: right;">Page 115</p> <p>1 particular attention to criticizing cohort 2 studies, with little acknowledgement to the 3 limitations of case-control studies that find 4 weak associations." 5 Did I read that correctly? 6 A. That's correct. 7 Q. Okay. So you think that there 8 is a hierarchy of evidence that is generally 9 accepted? 10 MS. MILLER: Objection. 11 THE WITNESS: It's not what I 12 think. There is a general hierarchy 13 of evidence -- 14 QUESTIONS BY MR. TISI: 15 Q. Okay. 16 A. -- in the epidemiologic 17 community -- 18 Q. Okay. 19 A. -- and so there are different 20 levels of evidence based on a study design. 21 Q. Okay. And on that -- under 22 that design hierarchy, cohort studies are 23 more reliable than case-control studies, as a 24 general matter? 25 MS. MILLER: Objection.</p>	<p style="text-align: right;">Page 117</p> <p>1 studies do show an association between talc 2 use and ovarian cancer, have found a relative 3 risk in the range of 1.2 to 1.6, this, by 4 definition, is a weak association." 5 Do you see that? 6 A. I do, yes. 7 Q. Okay. And you're critical of 8 their description of the strength of the 9 association? 10 A. Relative risk in the range of 11 1.2 to 1.6 is, by definition, a weak 12 association. 13 Q. Whose definition? 14 A. I think I have a reference in 15 here. 16 Q. Yeah, you have a reference to 17 an Australian white paper. 18 A. And in the epidemiology -- 19 epidemiologic community, a relative risk or 20 an odds ratio of less than 2 would be 21 considered a weak association -- 22 Q. Okay. 23 A. -- and very, very easy -- 24 easily -- with the susceptibility to be 25 easily explained away by bias or confounding,</p>

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<p>1 and that's why it's considered a weak 2 association. 3 Q. The next thing you say is, 4 "Likewise, plaintiffs' experts demonstrate a 5 dose-response relationship in relying on 6 methodologically flawed studies and 7 statistically insignificant trend lines." 8 A. That's correct. 9 Q. Okay. And then another thing 10 is you say, "They see consistency where the 11 studies are inherently inconsistent." 12 A. That's correct. 13 Q. Okay. So those are the four 14 main criticisms that you have? 15 MS. MILLER: Objection. 16 THE WITNESS: That's what it 17 says here, yeah. 18 (Merlo Exhibit 10 marked for 19 identification.) 20 QUESTIONS BY MR. TISI: 21 Q. Okay. So I have pulled 22 together -- so it will help us frame our 23 discussion today, I pulled those four, put 24 them on a slide, and I'm going to ask you to 25 look at it and tell me whether you agree that</p>	<p>1 explain on the record my objections to 2 this exhibit. 3 MR. TISI: Objection to form is 4 the question {sic}. 5 MS. MILLER: That's -- you 6 can't object to the form of an 7 exhibit. 8 MR. TISI: Fine. Objection. 9 MS. MILLER: Excuse me. Please 10 let me finish -- 11 MR. TISI: Objection. 12 MS. MILLER: -- my sentence. 13 You're being really rude to me. 14 MR. TISI: I'm being -- you 15 know, honestly, you have been so 16 unprofessional with every one of these 17 witnesses, and I have today pulled 18 together all of your objections over 19 the past couple of depositions, I've 20 put them on a spreadsheet, and I will 21 send them to judge -- to Judge Pisano 22 and have him look at whether or not 23 your objections comply with the CMO. 24 MS. SHARKO: Calm down. 25 MR. TISI: Okay. So if we're</p>
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<p>1 those -- I'm sorry. Can I have that one 2 back? That's my copy. 3 MS. MILLER: Yeah. 4 I'm going to object to this 5 exhibit. I think this pulls four 6 sentences out of a 46-page report. It 7 says "Merlo allegations," and Merlo's 8 not making allegations. He's -- 9 MR. TISI: Oh, he's making 10 plenty of allegations, and your 11 expert -- 12 MS. SHARKO: Don't interrupt. 13 MS. MILLER: Excuse me. 14 MR. TISI: I'm going to tell 15 you the -- Jessica, we're not going to 16 get into this. You've been -- 17 MS. MILLER: I'm going to 18 object to this exhibit -- 19 MR. TISI: So just say 20 "objection." 21 MS. MILLER: -- and I'm going 22 to explain -- no. 23 MR. TISI: No. You're not 24 going to. Objection. 25 MS. MILLER: I'm going to</p>	<p>1 going to -- if we're going to go down 2 this today as we did in the Shih 3 deposition, the Ballman deposition and 4 every other deposition in this case, 5 I'm going to pull them, I'm going to 6 send them to Judge Pisano, and we're 7 going to have a hearing. 8 MS. MILLER: I'm not going to 9 be intimidated by your threats. 10 MR. TISI: So let's just -- 11 let's just comply with the CMO and say 12 "objection." 13 MS. MILLER: This is an 14 inappropriate exhibit. 15 MR. TISI: Fine. Objection. 16 MR. LOCKE: I object as well. 17 QUESTIONS BY MR. TISI: 18 Q. Doctor, are those four 19 criticisms -- 20 MS. MILLER: Excuse me. Do you 21 have something to say? 22 MR. LOCKE: Yeah, I object as 23 well for the same bases. 24 MR. TISI: Okay. 25 MR. LOCKE: It doesn't even</p>

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<p>1 quote --</p> <p>2 MR. TISI: Tom --</p> <p>3 MR. LOCKE: -- what's there.</p> <p>4 MR. TISI: Tom, I'm asking</p> <p>5 him -- I haven't asked a question yet.</p> <p>6 MS. MILLER: It doesn't matter</p> <p>7 whether you've asked the question.</p> <p>8 We're objecting to the exhibit itself.</p> <p>9 MR. TISI: Fine.</p> <p>10 MS. MILLER: It's an</p> <p>11 inappropriate exhibit.</p> <p>12 MR. TISI: So just say</p> <p>13 objection.</p> <p>14 MS. SHARKO: I don't think we</p> <p>15 have to do that. If you're concerned</p> <p>16 about the witness hearing what we're</p> <p>17 saying, he can leave the room.</p> <p>18 MR. TISI: I'm happy to leave</p> <p>19 the room --</p> <p>20 MS. SHARKO: This is totally</p> <p>21 inappropriate, Mr. Tisi, and you know</p> <p>22 it.</p> <p>23 MR. TISI: I can provide him</p> <p>24 with a plate of spaghetti and ask him</p> <p>25 questions about it if I want to.</p>	<p>1 MR. LOCKE: Objection.</p> <p>2 MS. MILLER: Objection.</p> <p>3 THE WITNESS: I don't know what</p> <p>4 you mean by "serious charges."</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. Well, you say that each of</p> <p>7 plaintiffs' experts used Bradford Hill in a</p> <p>8 manner that was irregular and suggest</p> <p>9 results-driven approach.</p> <p>10 Do you remember that?</p> <p>11 MS. MILLER: Objection.</p> <p>12 THE WITNESS: Where are you</p> <p>13 referring to?</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Well, go to page 40, if you</p> <p>16 could, of your report.</p> <p>17 On your report, you use the</p> <p>18 phrase that "they jumped to causation without</p> <p>19 sufficiently determining association."</p> <p>20 That's a word you use. That's</p> <p>21 the -- that's Section C.</p> <p>22 Do you see that?</p> <p>23 A. It says, "Jumping to causation</p> <p>24 without sufficiently determining</p> <p>25 association."</p>
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<p>1 Okay? It's not inappropriate.</p> <p>2 MR. LOCKE: And it would be a</p> <p>3 complete waste of time.</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. Doctor, let me ask you: Are</p> <p>6 these four criticisms that are on that</p> <p>7 exhibit criticisms that you have of</p> <p>8 plaintiffs' experts?</p> <p>9 MS. MILLER: Objection.</p> <p>10 MR. LOCKE: Objection.</p> <p>11 MR. TISI: Can I have the</p> <p>12 spreadsheet that you made copies of</p> <p>13 today? Because I'm going to mark that</p> <p>14 as an exhibit.</p> <p>15 THE WITNESS: I didn't say</p> <p>16 these things.</p> <p>17 QUESTIONS BY MR. TISI:</p> <p>18 Q. Okay. So you disagree.</p> <p>19 Is there anything that I would</p> <p>20 need to make those things -- to make them</p> <p>21 accurate?</p> <p>22 A. It's all in my report.</p> <p>23 Q. Okay. So let's do this. You</p> <p>24 make serious charges against plaintiffs'</p> <p>25 experts in your report, do you not?</p>	<p>1 Q. Okay. So they jumped to</p> <p>2 causation.</p> <p>3 Is that a word that you used or</p> <p>4 is it a word that was provided to you by</p> <p>5 defense lawyers in this case?</p> <p>6 MS. MILLER: Objection.</p> <p>7 MR. LOCKE: Objection.</p> <p>8 THE WITNESS: Again, I didn't</p> <p>9 say "they." It just says, "C, jumping</p> <p>10 to causation without sufficiently</p> <p>11 determining association."</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. And then you describe what the</p> <p>14 plaintiffs' experts allegedly did, correct?</p> <p>15 A. It's all -- it's all in my</p> <p>16 report.</p> <p>17 Q. Okay. And on page 35 of your</p> <p>18 report, you say that they "ignored and</p> <p>19 disregarded well-established hierarchy."</p> <p>20 A. Which page? I'm sorry.</p> <p>21 Q. Page 35.</p> <p>22 And this is under the title of</p> <p>23 Methodologic Flaws in Plaintiffs' Experts'</p> <p>24 Epidemiology-Based Opinions, correct?</p> <p>25 A. Where are you referring to?</p>

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<p style="text-align: right;">Page 126</p> <p>1 Q. Right there.</p> <p>2 A. I know, but what -- I see that,</p> <p>3 Methodologic Flaws in Plaintiffs' Experts.</p> <p>4 Q. Right.</p> <p>5 And Section A is, "disregard</p> <p>6 for the hierarchy of evidence."</p> <p>7 A. Section A does say "disregard</p> <p>8 for the hierarchy of evidence."</p> <p>9 Q. And the third paragraph starts</p> <p>10 with, "A number of plaintiffs'</p> <p>11 epidemiologists ignore well-established</p> <p>12 hierarchy of evidence," correct?</p> <p>13 A. In my report it says, "A number</p> <p>14 of plaintiffs' epidemiologists ignore the</p> <p>15 well-established hierarchy of evidence."</p> <p>16 Q. And under the section that says</p> <p>17 Methodologic Flaws of Plaintiffs' Experts'</p> <p>18 Epidemiology-Based Opinions, you also say</p> <p>19 that they "fabricated consistency by ignoring</p> <p>20 studies that did not support their</p> <p>21 conclusion" on page 44, correct?</p> <p>22 A. And where is that on page 44?</p> <p>23 Q. Well, Section 2 says,</p> <p>24 "Plaintiffs' experts fabricate consistency by</p> <p>25 ignoring inconsistent studies."</p>	<p style="text-align: right;">Page 128</p> <p>1 fabrication?</p> <p>2 MS. MILLER: Objection.</p> <p>3 THE WITNESS: It says,</p> <p>4 "Plaintiffs' experts fabricate</p> <p>5 consistency by ignoring inconsistent</p> <p>6 studies."</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. And that is a pretty serious</p> <p>9 thing to say about another scientist, is it</p> <p>10 not?</p> <p>11 MS. MILLER: Objection.</p> <p>12 THE WITNESS: Not if it's not</p> <p>13 true.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Okay. And so your opinion is</p> <p>16 that these experts fabricated opinions?</p> <p>17 A. What this is saying is that</p> <p>18 plaintiffs' expert fabricate consistency, not</p> <p>19 fabricating an opinion; fabricate consistency</p> <p>20 when consistency does not exist.</p> <p>21 Q. Well, one of their opinions is</p> <p>22 that there is consistency, correct?</p> <p>23 MS. MILLER: Objection.</p> <p>24 THE WITNESS: There is</p> <p>25 opinions -- well, you'd have to show</p>
<p style="text-align: right;">Page 127</p> <p>1 A. It says Section 2, "Plaintiffs'</p> <p>2 experts fabricate consistency by ignoring</p> <p>3 inconsistent studies."</p> <p>4 Q. That is a very -- to charge</p> <p>5 another scientist with fabrication is a</p> <p>6 pretty serious charge, is it not?</p> <p>7 MR. LOCKE: Objection.</p> <p>8 MS. MILLER: Objection.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. It's not one that scientists</p> <p>11 make lightly, is it?</p> <p>12 A. I'm not fabri -- I'm not -- I'm</p> <p>13 not charging anyone with anything.</p> <p>14 Q. Well, you're saying that that's</p> <p>15 what they did, correct?</p> <p>16 You're saying that "plaintiffs'</p> <p>17 experts fabricated consistency by ignoring</p> <p>18 inconsistent results."</p> <p>19 A. The studies were inconsistent.</p> <p>20 Q. Okay.</p> <p>21 A. So to say that they're</p> <p>22 consistent is --</p> <p>23 Q. A fabrication?</p> <p>24 A. -- inconsistent.</p> <p>25 Q. And you're saying that's a</p>	<p style="text-align: right;">Page 129</p> <p>1 me who you're talking about and --</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Well, you wrote this, Doctor.</p> <p>4 You wrote this, Doctor. You wrote this,</p> <p>5 Doctor. Okay?</p> <p>6 You said that "plaintiffs'</p> <p>7 experts fabricate consistency by ignoring</p> <p>8 inconsistent studies."</p> <p>9 That was your words, correct?</p> <p>10 A. That's correct.</p> <p>11 Q. All right. Now, my question to</p> <p>12 you is: You are -- you know that plaintiffs'</p> <p>13 experts, using your words here, said that the</p> <p>14 studies were consistent.</p> <p>15 A. We'd have to go through each</p> <p>16 expert and look --</p> <p>17 Q. You've done that before today,</p> <p>18 right?</p> <p>19 A. But we'd have to do it today.</p> <p>20 Q. You've done that in preparation</p> <p>21 of this report?</p> <p>22 A. I've read all the reports.</p> <p>23 Q. Okay. And so you wouldn't say</p> <p>24 that "plaintiffs' experts fabricated</p> <p>25 consistency by ignoring inconsistent results"</p>



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<p style="text-align: right;">Page 130</p> <p>1 had you not actually done the work to make</p> <p>2 that conclusion, correct?</p> <p>3 A. I have read the expert --</p> <p>4 Q. Okay.</p> <p>5 A. -- reports, but for the purpose</p> <p>6 of today, we would have to --</p> <p>7 Q. I'm going to ask you that. I'm</p> <p>8 going to ask you that, Doctor.</p> <p>9 My question is: That's a</p> <p>10 pretty serious thing for one scientist to say</p> <p>11 about another.</p> <p>12 MS. MILLER: Objection.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. How would you -- how would you</p> <p>15 react if somebody said you -- that you</p> <p>16 fabricated your opinion in this case?</p> <p>17 MS. MILLER: Objection.</p> <p>18 THE WITNESS: I didn't say that</p> <p>19 there's fabrication of opinion. I</p> <p>20 said that's fabricating consistency,</p> <p>21 and that's a very different thing.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Okay. And you don't think that</p> <p>24 the experts in this case testified that they</p> <p>25 thought the studies were consistent?</p>	<p style="text-align: right;">Page 132</p> <p>1 medical evidence and the literature, there's</p> <p>2 tremendous inconsistency between study</p> <p>3 designs, cohort studies and case controls,</p> <p>4 and even within study designs.</p> <p>5 Q. Okay. And then --</p> <p>6 A. In looking at the difference</p> <p>7 between hospital-based case controls and</p> <p>8 population-based controls, there's</p> <p>9 inconsistency.</p> <p>10 Q. Okay. And we're going to talk</p> <p>11 about that. Okay. I promise you we're going</p> <p>12 to talk about that.</p> <p>13 But the question is: When you</p> <p>14 use a word like "fabrication," you would</p> <p>15 agree that that is a word that is -- has a</p> <p>16 particular understanding in science as being</p> <p>17 a very bad thing?</p> <p>18 MS. MILLER: Objection.</p> <p>19 THE WITNESS: I would neither</p> <p>20 agree nor disagree with that. I don't</p> <p>21 know even what you mean by "that's a</p> <p>22 very bad thing."</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. So if somebody said to you,</p> <p>25 "Doctor, your report contains fabricated</p>
<p style="text-align: right;">Page 131</p> <p>1 A. We'd have to look at each</p> <p>2 expert and go through. It's a very general</p> <p>3 question.</p> <p>4 Q. So you didn't do that before</p> <p>5 today?</p> <p>6 MS. MILLER: Objection.</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. You actually cite Moorman's</p> <p>9 report, Siemiatycki's report, Singh's report,</p> <p>10 McTiernan's report. You cited all these --</p> <p>11 all these here. And we can go through them,</p> <p>12 and I'm happy to go through them.</p> <p>13 But I'm asking you about your</p> <p>14 report. And this report says that it is --</p> <p>15 that it is your review -- they said it was</p> <p>16 consistent; you said that was fabricated.</p> <p>17 Right?</p> <p>18 MS. MILLER: Objection.</p> <p>19 THE WITNESS: What I say is,</p> <p>20 "plaintiffs' experts fabricate</p> <p>21 consistency by ignoring inconsistent</p> <p>22 studies."</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. Okay.</p> <p>25 A. And when we look at the body of</p>	<p style="text-align: right;">Page 133</p> <p>1 conclusions or fabricated methodologies,"</p> <p>2 would you not take that seriously?</p> <p>3 MS. MILLER: Objection.</p> <p>4 THE WITNESS: I don't know what</p> <p>5 a fabricated conclusion is or a</p> <p>6 fabricated methodology, sir.</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. You don't know what that is.</p> <p>9 But you used the word -- what</p> <p>10 did you mean by "fabrication"? The word</p> <p>11 "fabrication."</p> <p>12 What does the word</p> <p>13 "fabrication" mean to you?</p> <p>14 A. What I mean is plaintiffs'</p> <p>15 experts are making a case for consistency</p> <p>16 when consistency does not exist.</p> <p>17 Q. Okay. Well, you go on to say,</p> <p>18 Doctor, at the very last page, you say -- or</p> <p>19 the paragraph says, "As a professor of</p> <p>20 medicine and public health, I have focused my</p> <p>21 career using science of epidemiology as a</p> <p>22 scientific tool to help improve the</p> <p>23 understanding of health and disease. The</p> <p>24 distortion of epidemiologic science for</p> <p>25 purposes of litigation does not achieve those</p>



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<p style="text-align: right;">Page 134</p> <p>1 goals; instead, it undermines scientific</p> <p>2 efforts to better understand the etiology of</p> <p>3 disease."</p> <p>4 Is it your opinion that</p> <p>5 plaintiffs' experts distorted the</p> <p>6 epidemiologic science for purposes of</p> <p>7 litigation?</p> <p>8 MR. LOCKE: Objection.</p> <p>9 THE WITNESS: That's what I</p> <p>10 wrote in my report.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Did you mean to refer to</p> <p>13 plaintiffs' experts here?</p> <p>14 A. In any epidemiologic study --</p> <p>15 Q. I'm asking you this question.</p> <p>16 MS. MILLER: Please let him</p> <p>17 answer.</p> <p>18 THE WITNESS: In any</p> <p>19 epidemiologic study, if science is</p> <p>20 distorted for the purpose of</p> <p>21 litigation, it goes against --</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Right.</p> <p>24 A. -- what I've done in my --</p> <p>25 Q. And you're claiming that's what</p>	<p style="text-align: right;">Page 136</p> <p>1 disease."</p> <p>2 Q. Right.</p> <p>3 A. "The distortion of</p> <p>4 epidemiologic science for purposes of</p> <p>5 litigation does not achieve this goal."</p> <p>6 Q. Okay.</p> <p>7 A. "Instead, it undermines</p> <p>8 scientific efforts to better understand the</p> <p>9 etiology of disease."</p> <p>10 Q. We read that. Now I'm asking</p> <p>11 you a question about that.</p> <p>12 My question is: Is it your</p> <p>13 opinion that that's what the plaintiffs'</p> <p>14 experts did in this case?</p> <p>15 MS. MILLER: Objection.</p> <p>16 THE WITNESS: I don't know what</p> <p>17 the experts did in this case as far as</p> <p>18 with regards to that.</p> <p>19 What I can say is that the</p> <p>20 distortion of epidemiologic science</p> <p>21 for purposes of litigation does not</p> <p>22 achieve those goals.</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. Okay. I'm asking you this</p> <p>25 question. You have to answer this question.</p>
<p style="text-align: right;">Page 135</p> <p>1 defendants -- that that's what plaintiffs'</p> <p>2 experts did in this case.</p> <p>3 A. Can you say that again?</p> <p>4 Q. Yes.</p> <p>5 You say you don't do that,</p> <p>6 right?</p> <p>7 You don't distort the</p> <p>8 scientific evidence for the purposes of</p> <p>9 litigation, right?</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: Can you ask that</p> <p>12 question --</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. Yes.</p> <p>15 A. -- just a little slower?</p> <p>16 You're speaking very fast.</p> <p>17 Q. You say that -- you say, as a</p> <p>18 professor of medicine in public health, it's</p> <p>19 a bad thing to distort the epidemiologic</p> <p>20 evidence for litigation, true?</p> <p>21 A. What I say is, "As a professor</p> <p>22 of medicine in public health, I have focused</p> <p>23 my career on using the science of</p> <p>24 epidemiology as a scientific tool to help</p> <p>25 improve our understanding of health and</p>	<p style="text-align: right;">Page 137</p> <p>1 Okay?</p> <p>2 Is it your opinion, to a</p> <p>3 reasonable degree of medical and scientific</p> <p>4 certainty, that plaintiffs' experts distorted</p> <p>5 the epidemiologic science for the purposes of</p> <p>6 litigation?</p> <p>7 MR. LOCKE: Objection.</p> <p>8 THE WITNESS: So I believe I</p> <p>9 answered that already.</p> <p>10 I -- the methodology that was</p> <p>11 performed by plaintiffs' experts is</p> <p>12 flawed, and, therefore, my opinions in</p> <p>13 relation to the potential causal</p> <p>14 association between talcum powder and</p> <p>15 ovarian cancer -- when I think of --</p> <p>16 when I -- based on the body of medical</p> <p>17 evidence, there is no causal</p> <p>18 association between perineal talc</p> <p>19 usage and ovarian cancer.</p> <p>20 And the critique I have against</p> <p>21 plaintiffs' opinions relate to their</p> <p>22 methodology.</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. Right.</p> <p>25 And is it your opinion -- I</p>

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<p style="text-align: right;">Page 138</p> <p>1 understand you have a difference of opinion 2 on their methodology. But you take it one 3 step further, right? 4 You say it was their 5 methodology -- at least the implication is, 6 and I'm asking you the question: Are you 7 suggesting that they fabricated in a 8 methodology for the purposes of litigation? 9 MR. LOCKE: Objection. 10 MS. MILLER: Objection. Asked, 11 answered, mischaracterizes his 12 opinions and his testimony. 13 THE WITNESS: I believe I 14 answered that. 15 QUESTIONS BY MR. TISI: 16 Q. Okay. I want to hear about 17 your litigation -- I want to hear about what 18 your opinion is as the motivation for doing 19 what they did. 20 Is it your opinion that their 21 motive in drafting their reports and using 22 the methodology that they use was to assist 23 in litigation? 24 MS. MILLER: Objection. 25 THE WITNESS: I have no idea</p>	<p style="text-align: right;">Page 140</p> <p>1 QUESTIONS BY MR. TISI: 2 Q. So you have no idea what the 3 motive and intent of plaintiffs' experts were 4 in drafting their opinions, right? 5 A. I have no idea. 6 Q. Okay. Are you saying that the 7 methodology that they used was fraudulent? 8 MS. MILLER: Objection. 9 THE WITNESS: I don't think 10 that there's -- are you referring to 11 any part of my report that says 12 fraudulent? 13 QUESTIONS BY MR. TISI: 14 Q. I'm asking you your opinion -- 15 I'm asking your opinion right now, under 16 oath. 17 Are you saying that the 18 opinions that they offered was fraudulent? 19 MS. MILLER: Objection. 20 QUESTIONS BY MR. TISI: 21 Q. The methodology they used was 22 fraudulent? 23 A. Probably have to be a little 24 bit more specific. 25 Q. Tell me what your views are on</p>
<p style="text-align: right;">Page 139</p> <p>1 what their motivation was. 2 QUESTIONS BY MR. TISI: 3 Q. So then why is it in here? Why 4 is anything about litigation even in your 5 report, Doctor? 6 MR. LOCKE: Objection. 7 MS. MILLER: Objection. 8 THE WITNESS: Because if 9 epidemiologic science is distorted for 10 the purposes of litigation, it does 11 not achieve those goals. 12 QUESTIONS BY MR. TISI: 13 Q. And do you think that that's 14 what they did? 15 MS. MILLER: Objection. 16 THE WITNESS: I have no idea 17 what they did. 18 QUESTIONS BY MR. TISI: 19 Q. Okay. So you'd take that out 20 of this report? 21 MR. LOCKE: Objection. 22 MS. MILLER: Objection. 23 THE WITNESS: My report is my 24 report. It stands. 25</p>	<p style="text-align: right;">Page 141</p> <p>1 that. 2 A. Which expert are we talking 3 about? Which part of the methodology? 4 Which -- 5 Q. Okay. Do you think that 6 Dr. Siemiatycki applied a fraud -- a 7 professor of epidemiology applied -- who has 8 sat on IARC and looked at cancer and exposure 9 to disease applied a fraudulent methodology? 10 MR. LOCKE: Objection. 11 MS. MILLER: Objection. 12 THE WITNESS: No. I don't even 13 know what a fraudulent methodology is. 14 QUESTIONS BY MR. TISI: 15 Q. Okay. Do you think he applied 16 a litigation or results-driven methodology? 17 A. I don't -- I don't know what a 18 litigation -- I don't know what a litigation 19 methodology would be. 20 Q. Well, it says -- do you believe 21 that he distorted the epidemiologic 22 sciences -- science for the purpose of 23 litigation? 24 A. I never said that 25 Dr. Siemiatycki distorted epidemiologic</p>

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<p style="text-align: right;">Page 142</p> <p>1 science.</p> <p>2 Q. Okay. Do you think that</p> <p>3 Dr. McTiernan did?</p> <p>4 MS. MILLER: Objection.</p> <p>5 THE WITNESS: Can you ask that</p> <p>6 one more time?</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. Yes.</p> <p>9 Do you think that Dr. McTiernan</p> <p>10 distorted epidemiologic science?</p> <p>11 MS. MILLER: Objection.</p> <p>12 THE WITNESS: I have no idea.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. Okay. Do you think that</p> <p>15 Dr. Smith-Bindman distorted science?</p> <p>16 MS. MILLER: Objection.</p> <p>17 THE WITNESS: I don't know.</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. Do you think that Dr. Singh</p> <p>20 distorted science?</p> <p>21 A. The same answer stands.</p> <p>22 Q. Dr. Moorman, do you think she</p> <p>23 distorted science?</p> <p>24 MS. MILLER: Objection.</p> <p>25 THE WITNESS: I think -- I</p>	<p style="text-align: right;">Page 144</p> <p>1 shaking --</p> <p>2 MR. TISI: Okay. That's fine.</p> <p>3 MS. SHARKO: -- and I ask that</p> <p>4 you calm down.</p> <p>5 MR. TISI: I think it's -- I</p> <p>6 think -- you can ask if I'd calm down,</p> <p>7 but when this gentleman comes in here</p> <p>8 and says our experts fabricated,</p> <p>9 ignored, I take it personally.</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. I want to hear -- I want to</p> <p>12 ask -- I want to ask you this question,</p> <p>13 Doctor.</p> <p>14 MS. SHARKO: Well, I think</p> <p>15 you're misrepresenting his report, and</p> <p>16 he's told that you.</p> <p>17 MR. TISI: Well, if you are,</p> <p>18 then maybe -- maybe he ought to back</p> <p>19 down on some of the adjectives he</p> <p>20 uses.</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. Doctor, do you believe --</p> <p>23 MS. SHARKO: Do you need a</p> <p>24 break, Mr. Tisi?</p> <p>25 MR. TISI: No, I don't, Susan,</p>
<p style="text-align: right;">Page 143</p> <p>1 can't -- I can't speak to the</p> <p>2 motivations of someone else.</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. Do you believe that the same</p> <p>5 standards you would apply to plaintiffs'</p> <p>6 experts should apply to your opinions: You</p> <p>7 shouldn't fabricate; you shouldn't distort;</p> <p>8 you shouldn't ignore?</p> <p>9 MS. MILLER: Objection.</p> <p>10 That's --</p> <p>11 MR. TISI: Let the record</p> <p>12 reflect you're once again laughing.</p> <p>13 MS. MILLER: -- four questions.</p> <p>14 MS. SHARKO: I'm smiling.</p> <p>15 MR. TISI: You're laughing.</p> <p>16 MS. SHARKO: No. I think --</p> <p>17 MR. TISI: I don't ask -- I'm</p> <p>18 not asking her anything. The record</p> <p>19 will reflect is you were laughing.</p> <p>20 MS. SHARKO: The record will</p> <p>21 reflect that you are not asking him a</p> <p>22 single question like you're supposed</p> <p>23 to.</p> <p>24 You're barking things. You're</p> <p>25 raising your voice. Your hands are</p>	<p style="text-align: right;">Page 145</p> <p>1 but maybe you do.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Let me ask you this question,</p> <p>4 Doctor.</p> <p>5 Do you believe that the same</p> <p>6 standards that you apply to reviewing</p> <p>7 plaintiffs' experts in this report should</p> <p>8 apply to your report as well?</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: I believe that my</p> <p>11 opinion is made based on the body of</p> <p>12 medical evidence. And for someone to</p> <p>13 say that there is consistency when</p> <p>14 consistency doesn't exist, or strength</p> <p>15 of association when strength of</p> <p>16 association doesn't exist, or there is</p> <p>17 a dose response when dose response</p> <p>18 doesn't exist, that's ignoring the</p> <p>19 body of evidence.</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. Okay. And you would take issue</p> <p>22 if you ignored evidence of the strength of</p> <p>23 association, correct?</p> <p>24 MS. MILLER: Objection.</p> <p>25</p>

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<p style="text-align: right;">Page 146</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. If you ignored evidence of</p> <p>3 consistency, if you ignored evidence of dose</p> <p>4 response, you would be subject to the same</p> <p>5 criticism. You would hold yourself up to no</p> <p>6 different scrutiny than you would imply --</p> <p>7 you would impose on plaintiffs' experts,</p> <p>8 agreed?</p> <p>9 MS. MILLER: Objection. There</p> <p>10 was a question, and before he could</p> <p>11 answer it, you asked another question.</p> <p>12 MR. LOCKE: Objection.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. Would you agree that you should</p> <p>15 not fabricate inconsistency when there is</p> <p>16 consistency?</p> <p>17 MS. MILLER: Objection.</p> <p>18 THE WITNESS: If we just go</p> <p>19 back to the medical evidence in this</p> <p>20 specific case, the fact that there is</p> <p>21 no strength of association or --</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. I'm not asking you that</p> <p>24 question. Doctor, I'm going to move to</p> <p>25 strike it. And honestly, we're going to</p>	<p style="text-align: right;">Page 148</p> <p>1 A. I don't know what that means.</p> <p>2 Q. Okay. Do you think you should</p> <p>3 not fabricate a methodology for the purposes</p> <p>4 of litigation?</p> <p>5 MS. MILLER: Objection.</p> <p>6 THE WITNESS: I never said</p> <p>7 fabricating methodology.</p> <p>8 QUESTIONS BY MR. TISI:</p> <p>9 Q. Okay. Do you think that you</p> <p>10 should not -- you should not ignore evidence</p> <p>11 and well-established principles?</p> <p>12 MS. MILLER: Objection.</p> <p>13 THE WITNESS: Can you ask that</p> <p>14 one more time?</p> <p>15 MR. TISI: Yeah.</p> <p>16 THE WITNESS: I'm not sure I</p> <p>17 understood what that --</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. Do you think you should not</p> <p>20 ignore evidence?</p> <p>21 Should you ignore evidence?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: I mean, in</p> <p>24 looking at the causal association</p> <p>25 between exposure and outcome, we try</p>
<p style="text-align: right;">Page 147</p> <p>1 need -- we may need to take a break on this</p> <p>2 because you need to listen to my question.</p> <p>3 My question is: Would you hold</p> <p>4 yourself to the same standards that you have</p> <p>5 criticized the plaintiffs' experts for?</p> <p>6 I'm not asking about the</p> <p>7 evidence in this case.</p> <p>8 Scientifically, would you agree</p> <p>9 that you should not -- you should not ignore</p> <p>10 consistency when it exists?</p> <p>11 MS. MILLER: Objection.</p> <p>12 THE WITNESS: Can you ask that</p> <p>13 one more time?</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Yes.</p> <p>16 Do you agree that you should</p> <p>17 not fabricate an opinion?</p> <p>18 MS. MILLER: Objection.</p> <p>19 THE WITNESS: I don't know what</p> <p>20 that means.</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. You don't know -- well, you</p> <p>23 used the word "fabrication." It's your word.</p> <p>24 A. Well, fabricate an opinion.</p> <p>25 Q. Yes.</p>	<p style="text-align: right;">Page 149</p> <p>1 to look at all the evidence.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Do you know Sonal Singh?</p> <p>4 A. No.</p> <p>5 Q. He previously worked at</p> <p>6 Hopkins.</p> <p>7 Did he distort science?</p> <p>8 MS. MILLER: Objection.</p> <p>9 THE WITNESS: I have no idea.</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. Okay. Now, let me see if I</p> <p>12 can...</p> <p>13 As you know, I represent women</p> <p>14 who claim to have developed ovarian cancer as</p> <p>15 a result of using talcum powder products.</p> <p>16 You understand that, correct?</p> <p>17 MR. LOCKE: Objection.</p> <p>18 THE WITNESS: If you're telling</p> <p>19 me that, that's fine.</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. Okay. You were first consulted</p> <p>22 in this case in December of 2019 {sic},</p> <p>23 correct?</p> <p>24 MS. MILLER: Objection. Asked</p> <p>25 and answered multiple times.</p>

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<p style="text-align: right;">Page 150</p> <p>1 THE WITNESS: Somewhere around 2 there. I don't remember the specific 3 time. 4 MS. MILLER: Please let me 5 finish my objections. 6 QUESTIONS BY MR. TISI: 7 Q. Prior to being contacted by the 8 lawyers -- 9 MS. SHARKO: I assume you mean 10 December 2018. 11 MR. TISI: 2018. 12 QUESTIONS BY MR. TISI: 13 Q. Prior to being contacted by the 14 lawyers representing Johnson &amp; Johnson to 15 defend them in lawsuits, you had never 16 expressed the causation opinions, any of the 17 information in Exhibit Number 3, correct, 18 other than the general principles of 19 epidemiology? Any -- let me rephrase the 20 question. 21 Prior to December of 2018, you 22 had never expressed opinions about talc and 23 ovarian cancer, true? 24 A. That's about right. 25 Q. Okay. And you do know that the</p>	<p style="text-align: right;">Page 152</p> <p>1 A. There are hospital-based 2 case-control studies. There are 3 population-based case-control studies, pool 4 case-control studies, cohort studies. 5 Q. They go from the 1980s, 1990s, 6 2000s and 2010s. Four decades, correct? 7 A. Spanning 1982 through 2016 for 8 these studies that we're talking about right 9 here. 10 Q. Were you involved in any of 11 these studies in any way even peripherally? 12 A. I was not. 13 Q. Okay. Had anybody in this 14 period of time ever contacted you and said, 15 "You know, we have this issue out there about 16 whether or not talcum powder products are 17 associated with ovarian cancer; could you 18 consult with us on that question?" 19 MS. MILLER: Objection. 20 THE WITNESS: What period of 21 time are we talking about? 22 QUESTIONS BY MR. TISI: 23 Q. 1982 till today. 24 Other than the lawyers. 25 A. Can you ask me that question</p>
<p style="text-align: right;">Page 151</p> <p>1 epidemiologic -- the first epidemiologic 2 study was published by researchers at Harvard 3 University in 1982, correct? 4 MS. MILLER: Objection. 5 THE WITNESS: I would have to 6 look back through the -- through my 7 report and see where those researchers 8 are from. 9 (Merlo Exhibit 12 marked for 10 identification.) 11 QUESTIONS BY MR. TISI: 12 Q. Well, let me provide you with a 13 copy of an article by Cramer, et al. 14 You've seen this study before, 15 correct? 16 A. Cramer, yes, 1982. 17 Q. Okay. And you were just 18 looking at your chart on page 34 and 35 of 19 the various studies, correct? 20 A. That's correct. 21 Q. Okay. There are over 30 22 studies that you identified here, 23 hospital-based, population-based, 24 case-control studies, pooled case-control 25 studies and cohort studies, correct?</p>	<p style="text-align: right;">Page 153</p> <p>1 again then? 2 Q. Yeah. 3 From 1982 until today, has 4 anybody, other than the lawyers for Johnson &amp; 5 Johnson, ever asked you your opinions about 6 ovarian cancer and talcum powder products? 7 MS. MILLER: Objection. 8 THE WITNESS: Well, I believe I 9 answered that already, because I told 10 you when I was first approached to see 11 if I could offer an opinion. 12 QUESTIONS BY MR. TISI: 13 Q. That's a different question. 14 My question is: Outside of 15 lawyers, outside of lawyers in litigation, 16 has any scientist ever come up to you and 17 said, "Dr. Merlo, you are a epidemiologist 18 and a pulmonary and critical care professor 19 at Johns Hopkins. I'd like you to give me 20 your thoughts on the relationship between 21 ovarian cancer and talcum powder products." 22 MS. MILLER: Objection. 23 THE WITNESS: No one has asked 24 me to give an opinion in that time 25 period from 1982 to 2016.</p>

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<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. Has anyone ever consulted you</p> <p>3 and said, "What do you think about these</p> <p>4 studies?"</p> <p>5 A. No.</p> <p>6 Q. Has anyone ever said to you,</p> <p>7 "Doctor, you know, the evidence is really</p> <p>8 unclear; can you help us design a study?"</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: No.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Has anybody ever come to you</p> <p>13 from Johnson &amp; Johnson and say, "You know, we</p> <p>14 have these different regulatory bodies</p> <p>15 looking at the issue, NTP, the National</p> <p>16 Toxicology Project, IARC, the FDA, Health</p> <p>17 Canada, looking at this issue; would you come</p> <p>18 help us explain to these various regulatory</p> <p>19 bodies what the science is about talc and</p> <p>20 ovarian cancer?"</p> <p>21 MS. MILLER: Objection.</p> <p>22 THE WITNESS: No, but I would</p> <p>23 have been excited to do it.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. You know that Congress just</p>	<p>1 to express your opinions to the United States</p> <p>2 Congress about the relationship between</p> <p>3 ovarian cancer and talcum powder products?</p> <p>4 MS. MILLER: Objection.</p> <p>5 THE WITNESS: No. No. But</p> <p>6 again, I would have been excited to do</p> <p>7 something like that.</p> <p>8 QUESTIONS BY MR. TISI:</p> <p>9 Q. Did any scientist at Johnson &amp;</p> <p>10 Johnson ever come to you and say, "You know,</p> <p>11 we have" -- you understand Health Canada has</p> <p>12 reviewed the evidence, correct?</p> <p>13 A. I don't have -- I don't know</p> <p>14 anything about Health Canada.</p> <p>15 Q. Okay. Health Canada, you know,</p> <p>16 is the Canadian equivalent to the United</p> <p>17 States FDA?</p> <p>18 MR. LOCKE: Objection.</p> <p>19 MS. MILLER: Objection.</p> <p>20 THE WITNESS: I have no idea</p> <p>21 what Health Canada is.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Okay. And have you ever been</p> <p>24 asked by the scientists, as opposed to the</p> <p>25 lawyers at Johnson &amp; Johnson, to express your</p>
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<p>1 held a hearing on the issue of ovarian cancer</p> <p>2 and talcum powder products, correct?</p> <p>3 A. I have no idea.</p> <p>4 Q. You know Dr. McTiernan appeared</p> <p>5 before -- appeared before the House of</p> <p>6 Representatives to express her opinions in a</p> <p>7 public forum, correct?</p> <p>8 MS. MILLER: Objection.</p> <p>9 THE WITNESS: Again, I have no</p> <p>10 idea.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Do you know that -- did Johnson</p> <p>13 &amp; Johnson ever ask you, "You know, Dr. Merlo,</p> <p>14 we need somebody to present our point of view</p> <p>15 on what the science says. Would you go</p> <p>16 testify before Congress?"</p> <p>17 Did they tell you that?</p> <p>18 MS. MILLER: Objection.</p> <p>19 THE WITNESS: Did they tell me</p> <p>20 what?</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. Did they ask you to do that?</p> <p>23 MS. MILLER: Objection. Vague.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. Did Johnson &amp; Johnson ask you</p>	<p>1 opinion before any regulatory or professional</p> <p>2 body on the relationship between ovarian</p> <p>3 cancer and talcum powder products?</p> <p>4 MS. MILLER: Objection.</p> <p>5 THE WITNESS: No, and I believe</p> <p>6 I've answered this before, but I would</p> <p>7 have been -- having reviewed the</p> <p>8 literature, I would be really excited</p> <p>9 to do that.</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. Uh-huh. Let me ask you this,</p> <p>12 Doctor -- maybe Ms. Sharko will ask you to do</p> <p>13 it after this deposition. We'll find out.</p> <p>14 Has Johnson &amp; Johnson ever come</p> <p>15 to you and asked you, we have -- to do a</p> <p>16 causation analysis on any issue, on any</p> <p>17 product it markets?</p> <p>18 A. They have not.</p> <p>19 Q. And you know Johnson &amp;</p> <p>20 Johnson's a big company. They produce --</p> <p>21 they produce pharmaceutical drugs. They</p> <p>22 produce cosmetics. They produce</p> <p>23 over-the-counter drugs. They produce all</p> <p>24 kinds of drugs, right?</p> <p>25 MS. MILLER: Objection.</p>

40 (Pages 154 to 157)



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<p style="text-align: right;">Page 158</p> <p>1 THE WITNESS: I have no idea.  2 I mean, I know of Johnson &amp; Johnson,  3 but I don't have an opinion on what  4 they do or have really any knowledge  5 on what they do.  6 QUESTIONS BY MR. TISI:  7 Q. And other than the litigation,  8 they never came to you to ask your advice on  9 anything, true?  10 MS. MILLER: Objection.  11 THE WITNESS: I think we've  12 talked about that. They didn't ask me  13 to do anything.  14 QUESTIONS BY MR. TISI:  15 Q. Now, in this case, literally  16 millions of documents have been produced --  17 millions of pages of documents have been  18 produced to us.  19 Would it surprise you that the  20 name Christian Merlo doesn't appear in any of  21 them?  22 MS. MILLER: Objection.  23 THE WITNESS: I don't know what  24 you're referring to.  25</p>	<p style="text-align: right;">Page 160</p> <p>1 done on this issue, have you ever either been  2 approached or approached Johnson &amp; Johnson  3 and said, "You know something, I'm an expert  4 in design of studies. Let me help you design  5 a study that would -- that would answer this  6 question once and for all"?  7 MS. MILLER: Objection.  8 QUESTIONS BY MR. TISI:  9 Q. Has that ever happened?  10 MS. MILLER: Objection.  11 THE WITNESS: Excuse me. That  12 has not happened.  13 QUESTIONS BY MR. TISI:  14 Q. Okay.  15 A. However, I would gladly like to  16 be involved in something like that.  17 Q. Okay.  18 A. I think the key issue here in  19 designing a clinical study like that is there  20 are a lot of difficulties.  21 Q. Well, you can't do a clinical  22 trial on this issue, can you?  23 A. Well, it depends what you mean  24 by a clinical trial, because clinical trials  25 can be cohort studies; they can be</p>
<p style="text-align: right;">Page 159</p> <p>1 QUESTIONS BY MR. TISI:  2 Q. Millions of pages of documents  3 relating to research and marketing and  4 evidence and -- about ovarian cancer and its  5 relationship to talcum powder products, the  6 composition of talcum powder, all kinds of  7 issues, have been produced to us in this  8 case.  9 Would it surprise you that your  10 name doesn't appear even once over the past  11 40 or 50 years of documents that we've  12 received?  13 MR. LOCKE: Objection.  14 THE WITNESS: No, it wouldn't  15 surprise me, but my opinion on this  16 and the potential association --  17 potential causal association between  18 talcum powder and ovarian cancer is  19 based on the medical literature.  20 QUESTIONS BY MR. TISI:  21 Q. Okay. Have the scientists at  22 Johnson &amp; Johnson ever reached out to you and  23 said -- even as of today, even as of the day  24 you wrote this report criticizing the various  25 studies that have been done in this case,</p>	<p style="text-align: right;">Page 161</p> <p>1 case-control studies.  2 Q. Understood.  3 You cannot randomize patients  4 to receiving talcum powder products, and it  5 would be unethical and unfeasible to study  6 this question using a randomized, controlled,  7 placebo-controlled trial?  8 A. It would be very difficult to  9 perform a randomized controlled trial.  10 Q. It would also be -- it would  11 not only be difficult, it would be unethical  12 if the hypothesis was to assess whether or  13 not talcum powder products cause ovarian  14 cancer?  15 A. Usually when randomized  16 controlled trials are designed, by  17 definition, if there is a -- if you're  18 testing a hypothesis that something is  19 causing something, usually you wouldn't  20 perform a randomized controlled trial.  21 Q. It would be unethical. There  22 are rules against that, correct?  23 MS. MILLER: Objection.  24 THE WITNESS: There are rules  25 against randomized controlled trials</p>

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<p style="text-align: right;">Page 162</p> <p>1 when the hypothesis is that you're</p> <p>2 going to cause -- there is the</p> <p>3 potential to cause harm.</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. Right.</p> <p>6 So it's not -- it's not -- you</p> <p>7 would not expect to see clinical trials in a</p> <p>8 setting like this?</p> <p>9 A. Again, these are -- there are</p> <p>10 clinical trials that have been done, but we</p> <p>11 wouldn't expect to see a randomized</p> <p>12 controlled trial performed here.</p> <p>13 Q. Okay. And you would agree with</p> <p>14 me that in circumstances like this, what</p> <p>15 typically experts have are epidemiology</p> <p>16 studies, observational studies.</p> <p>17 MS. MILLER: Can you just ask</p> <p>18 that again?</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. You want me to answer {sic}</p> <p>21 again?</p> <p>22 A. If you could ask me again, yes,</p> <p>23 please.</p> <p>24 Q. Do you -- where the question is</p> <p>25 whether or not an environmental factor or a</p>	<p style="text-align: right;">Page 164</p> <p>1 provide us with potential evidence when</p> <p>2 looking at the association between exposure</p> <p>3 and outcome.</p> <p>4 Q. Okay. Has the FDA ever reached</p> <p>5 out to you and asked your opinions on the</p> <p>6 question of whether or not talc causes</p> <p>7 ovarian cancer?</p> <p>8 A. The FDA has not.</p> <p>9 Q. Okay. You know IARC?</p> <p>10 A. I know what IARC stands for,</p> <p>11 but I don't know IARC.</p> <p>12 Q. Okay. Do you -- have you --</p> <p>13 has the International Agency for Research on</p> <p>14 Cancer, IARC, ever contacted you for any</p> <p>15 reason to ask you to be involved in any</p> <p>16 assessment of any exposure and cancer?</p> <p>17 A. They have not.</p> <p>18 Q. Have you written Health Canada</p> <p>19 to express your opinions that you've given in</p> <p>20 your report?</p> <p>21 MS. MILLER: Objection.</p> <p>22 THE WITNESS: Again, I don't</p> <p>23 really know who Health Canada is.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. Have you been provided with</p>
<p style="text-align: right;">Page 163</p> <p>1 substance causes harm, what science typically</p> <p>2 relies on are observational studies and</p> <p>3 biologic studies because you can't do</p> <p>4 controlled trials?</p> <p>5 MS. MILLER: Objection.</p> <p>6 THE WITNESS: Okay. Again, we</p> <p>7 have to just separate clinical trials.</p> <p>8 That involves everything.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Right.</p> <p>11 A. So if we're talking about an</p> <p>12 observational study, for instance, if I'm</p> <p>13 looking at a -- how a certain infectious</p> <p>14 agent might affect an outcome in a patient</p> <p>15 with cystic fibrosis, I wouldn't necessarily</p> <p>16 do a randomized control trial where I give</p> <p>17 someone an infection and I don't give</p> <p>18 somebody else -- give another group an</p> <p>19 infection and I look at an outcome</p> <p>20 afterwards.</p> <p>21 Q. Right.</p> <p>22 A. So when there is a potential</p> <p>23 for harm, a randomized control trial is</p> <p>24 usually not done, so we rely on observational</p> <p>25 studies, cohort and case-control studies, to</p>	<p style="text-align: right;">Page 165</p> <p>1 Health Canada's draft report on talcum powder</p> <p>2 and ovarian cancer?</p> <p>3 MS. MILLER: Objection. I</p> <p>4 don't know what that means.</p> <p>5 MR. TISI: You don't have to,</p> <p>6 Counsel.</p> <p>7 THE WITNESS: Is there</p> <p>8 something that you want to show me?</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Yeah. Sure.</p> <p>11 A. We can look at it.</p> <p>12 (Merlo Exhibit 13 marked for</p> <p>13 identification.)</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Showing you what I have marked</p> <p>16 as Exhibit Number 13.</p> <p>17 Have you seen this document</p> <p>18 before?</p> <p>19 A. I don't know.</p> <p>20 Q. Is it of interest to you --</p> <p>21 MS. MILLER: Do you need some</p> <p>22 time to flip through it?</p> <p>23 THE WITNESS: I think so.</p> <p>24 MR. TISI: No, I'm not -- I'm</p> <p>25 not asking -- I'm asking if he ever</p>

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<p style="text-align: right;">Page 166</p> <p>1 saw it -- Counsel, you know, honestly, 2 you really need to stop. You are 3 among the most unprofessional people I 4 have ever seen objecting in a case. 5 You inject yourself into almost every 6 question. 7 MR. LOCKE: Objection. 8 MS. SHARKO: Your ad hominem 9 and personal attacks -- 10 MR. TISI: Counsel, I was 11 called at the last deposition -- 12 MS. SHARKO: -- and venomous 13 comments, Mr. Tisi, are inappropriate. 14 MR. TISI: I was called -- 15 MS. SHARKO: Stop it 16 immediately. 17 MR. TISI: I was called at the 18 last deposition I was kicking her 19 under the table. I was called that I 20 speak to her as a -- you know, that I 21 speak to women this way. 22 Please don't talk to me about 23 ad hominem attacks. 24 MS. SHARKO: Well, those other 25 things you said are true. You were</p>	<p style="text-align: right;">Page 168</p> <p>1 THE WITNESS: Can you ask that 2 one more time? 3 QUESTIONS BY MR. TISI: 4 Q. Yeah. 5 Is it of interest to you what 6 other scientists and regulators have said 7 about the question you were asked to address 8 outside of litigation? 9 A. I'm curious about what others 10 say; however, in my review of the body of 11 medical literature that is out there today in 12 the published, peer-review literature, my 13 opinions are based on that. 14 Q. Okay. 15 A. I'm curious about other things, 16 but my opinions are based on what is peer 17 reviewed and published. 18 Q. Have you looked to see what 19 others have said about the body of evidence? 20 A. I don't know what you mean by 21 "others." 22 Q. Other scientists? Other 23 regulatory bodies? 24 A. You'd have to be more specific. 25 Q. Example, Health Canada?</p>
<p style="text-align: right;">Page 167</p> <p>1 kicking her. 2 MR. TISI: Oh, okay. I was not 3 kicking her under the table, and you 4 know that that's true -- not true. 5 MR. LOCKE: The witness is 6 entitled to read -- 7 MR. TISI: I'm not asking him a 8 question about the document. I'm 9 asking whether he ever saw the 10 document. 11 MS. MILLER: He needs to review 12 it to know if he ever saw it. 13 MR. TISI: No. I'm asking him 14 the questions. 15 MS. MILLER: Okay. 16 THE WITNESS: I'm looking to 17 see if I've seen this before. 18 I don't know. 19 QUESTIONS BY MR. TISI: 20 Q. Okay. Is it of interest to you 21 how other people outside of litigation, other 22 scientists, have evaluated the question of 23 whether or not talcum powder products cause 24 ovarian cancer? 25 MS. MILLER: Objection.</p>	<p style="text-align: right;">Page 169</p> <p>1 A. Health Canada? And again, I 2 have no idea who Health Canada is, whether or 3 not -- who is involved in Health Canada, 4 whether or not there are scientists involved, 5 whether or not -- who's there. I have no 6 idea. 7 Q. How about IARC? Did you review 8 the IARC 2010 report? 9 You were reviewing evidence 10 through 2006. Did you look at that? 11 A. Can you say that again? You 12 said two dates. 13 Q. Yes. 14 There was a 2010 report looking 15 at evidence up to 2006. 16 Did you look at that report? 17 A. I believe I did review that. 18 Q. And did you look any other 19 place to see what other scientists and 20 doctors have said about the issue? 21 A. Again, my job is not to have 22 opinions about other doctors or scientists. 23 My job is to give an opinion based on the 24 body of medical evidence, and that's what I 25 did.</p>

43 (Pages 166 to 169)

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<p style="text-align: right;">Page 170</p> <p>1 Q. Did you seek epidemio -- input 2 from your epidemiologic colleagues at Johns 3 Hopkins? 4 A. I seek -- I seek help from 5 epidemiologists all the time. 6 Q. For this report? 7 A. No. 8 Q. Okay. Did you speak to 9 Dr. Diette about your opinions in this case? 10 A. No. 11 Q. Did you speak to Dr. Szklo? Is 12 that his name? 13 A. Yeah. No. 14 Q. Did you speak to him? 15 A. No. No. 16 Q. Did you get permission of 17 approval from Johns Hopkins to participate in 18 this litigation? 19 MS. MILLER: Objection. 20 THE WITNESS: That's not 21 something that I would need approval 22 through Johns Hopkins for. 23 (Merlo Exhibit 14 marked for 24 identification.) 25</p>	<p style="text-align: right;">Page 172</p> <p>1 report. 2 A. I see it there on page 30. 3 Q. Yeah. So now can we agree it's 4 a seminal article? 5 MS. MILLER: Objection. 6 THE WITNESS: Well, it says, 7 "As Hill noted his seminal article." 8 QUESTIONS BY MR. TISI: 9 Q. So why was that such a hard 10 question to ask when -- answer when I asked 11 you what your opinion was? 12 MR. LOCKE: Objection. 13 MS. MILLER: Objection. 14 QUESTIONS BY MR. TISI: 15 Q. Did you need to see it in your 16 report in order to say what it says? 17 MS. MILLER: Objection. 18 THE WITNESS: I didn't 19 specifically remember saying that. 20 QUESTIONS BY MR. TISI: 21 Q. Okay. It doesn't matter 22 because my question was, is it a seminal 23 article? I didn't ask you whether you said 24 it in your report. 25 Why is it so hard to answer a</p>
<p style="text-align: right;">Page 171</p> <p>1 QUESTIONS BY MR. TISI: 2 Q. Going back to your opinions 3 about talc, I'd like to attach as Exhibit 14 4 the Bradford Hill article I think you had in 5 front of you, but I'm going to attach it as 6 Exhibit Number 14. 7 A. Thank you. 8 Q. Is this the Bradford Hill 9 article that you have been referring to? 10 A. This is one of many of Bradford 11 Hill's articles. 12 Q. Okay. 13 A. This is his discussion of 14 the -- what we call nowadays the Bradford 15 Hill analysis. 16 Q. This is what you called the 17 seminal article, right? 18 MR. LOCKE: Objection. 19 MS. MILLER: Objection. 20 THE WITNESS: Did I say that? 21 QUESTIONS BY MR. TISI: 22 Q. Yes, you did. 23 I don't know why that's a hard 24 question to answer, Doctor. Either you agree 25 to that or you don't, but it is in your</p>	<p style="text-align: right;">Page 173</p> <p>1 simple question as whether or not this is a 2 seminal article? 3 MS. MILLER: Objection. 4 Is that actually a question 5 you're asking? 6 MR. TISI: Yes. Absolutely. 7 QUESTIONS BY MR. TISI: 8 Q. Why is it so hard to answer 9 that question? 10 MS. MILLER: Objection. 11 MR. LOCKE: Objection. 12 QUESTIONS BY MR. TISI: 13 Q. Without seeing it in your 14 report? 15 MS. MILLER: Objection. 16 Now that the question has been 17 amended, still objection. 18 THE WITNESS: I thought you had 19 asked me if I said it, and I couldn't 20 remember -- 21 QUESTIONS BY MR. TISI: 22 Q. No. 23 A. -- if I actually said it. 24 Q. Actually, I asked you about ten 25 times: Is this a seminal article?</p>

44 (Pages 170 to 173)

<p style="text-align: right;">Page 174</p> <p>1 And why is that such a hard</p> <p>2 question to answer?</p> <p>3 MS. MILLER: Objection.</p> <p>4 MR. LOCKE: Objection.</p> <p>5 THE WITNESS: It's probably one</p> <p>6 of his seminal articles.</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. Okay. You didn't address the</p> <p>9 question of biologic plausibility in your</p> <p>10 report, did you?</p> <p>11 A. So I did not speak about</p> <p>12 biologic plausibility in my report.</p> <p>13 Q. Okay. Did you -- I'm sorry.</p> <p>14 A. And -- you can go ahead.</p> <p>15 Q. Did you address the question of</p> <p>16 specificity?</p> <p>17 A. There are several aspects of</p> <p>18 the Bradford Hill considerations that are</p> <p>19 inherently irrelevant in the analysis.</p> <p>20 And the reason for that is if</p> <p>21 we -- if we just back up a little bit, first</p> <p>22 of all, Bradford Hill said that you need to</p> <p>23 have a clearcut association before even going</p> <p>24 into that and --</p> <p>25 Q. Aren't there plenty of examples</p>	<p style="text-align: right;">Page 176</p> <p>1 you?</p> <p>2 It's the second paragraph.</p> <p>3 A. I see that.</p> <p>4 Q. Right.</p> <p>5 What does the first paragraph</p> <p>6 say?</p> <p>7 A. We can read it if you'd like.</p> <p>8 Q. Why don't you.</p> <p>9 A. "I have no wish, nor the skill,</p> <p>10 to embark upon a philosophical discussion of</p> <p>11 the meaning of causation. The cause of</p> <p>12 illness may be immediate, indirect, it may be</p> <p>13 remote and indirect, underlying the observed</p> <p>14 association, but with the aims of</p> <p>15 occupational and almost synonymously</p> <p>16 preventive medicine in mind, the decisive</p> <p>17 question is whether the frequency of the</p> <p>18 undesirable event, B, will be influenced by a</p> <p>19 change in the environmental factor, A. How</p> <p>20 such a change exerts that influence may call</p> <p>21 for a great deal of research. However,</p> <p>22 before deducing causation and taking action,</p> <p>23 we shall not have invariably have to sit</p> <p>24 around awaiting the results of that research.</p> <p>25 The whole chain may have to be unraveled or a</p>
<p style="text-align: right;">Page 175</p> <p>1 of cases where an exposure -- there is no</p> <p>2 epidemiology studies where there is a</p> <p>3 clearcut association?</p> <p>4 I'll give you an example:</p> <p>5 Acetaminophen and liver disease, do you know</p> <p>6 of any epidemiology study which establishes</p> <p>7 that risk?</p> <p>8 MS. MILLER: Objection.</p> <p>9 THE WITNESS: I'm not here to</p> <p>10 give an opinion on --</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. I know. But I want to know --</p> <p>13 A. -- acetaminophen and liver</p> <p>14 disease. I'd have to review the literature.</p> <p>15 Q. Well, where is your assessment?</p> <p>16 Where is the statement that</p> <p>17 before you apply the Bradford Hill factors</p> <p>18 that there must be a clearcut association?</p> <p>19 MS. MILLER: Objection.</p> <p>20 THE WITNESS: It's actually</p> <p>21 said right in his article.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Actually, let's talk about that</p> <p>24 because you quoted part of the sentence</p> <p>25 there. You didn't quote the whole thing, did</p>	<p style="text-align: right;">Page 177</p> <p>1 few links may suffice. It will depend on</p> <p>2 circumstances."</p> <p>3 Q. Okay. So and circumstances</p> <p>4 are, there are sometimes we have a lot of</p> <p>5 evidence on one factor and a lot of evidence</p> <p>6 on another factor, right?</p> <p>7 MS. MILLER: Objection.</p> <p>8 QUESTIONS BY MR. TISI:</p> <p>9 Q. These are considerations. No</p> <p>10 one is more important than the other. And</p> <p>11 that was Dr. -- Sir Bradford Hill's point,</p> <p>12 right? These are considerations?</p> <p>13 MS. MILLER: Objection.</p> <p>14 THE WITNESS: Once there is a</p> <p>15 clearcut association. And without</p> <p>16 that clearcut association, one could</p> <p>17 make the case of not even performing a</p> <p>18 Bradford Hill analysis.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. Okay. One can make the case;</p> <p>21 is that what he says?</p> <p>22 A. What he says is that in -- "in</p> <p>23 looking at causation, our observations reveal</p> <p>24 an association between two variables,</p> <p>25 perfectly clearcut and beyond what we would</p>



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<p style="text-align: right;">Page 178</p> <p>1 care to attribute the play of chance."  2 Q. Now, before we discuss your  3 experience any further, I want to ask you to  4 go back to the front page of your report.  5 The front page of your report,  6 Exhibit 3, says -- actually, let me just go  7 back and ask this question.  8 On the Bradford Hill, you said  9 you didn't discuss the biologic evidence with  10 respect to talc and ovarian cancer, and it's  11 not in your report, correct?  12 MS. MILLER: Objection.  13 THE WITNESS: I did not.  14 QUESTIONS BY MR. TISI:  15 Q. Okay. Did you -- I'm sorry, I  16 thought you were finished.  17 A. No, I did not discuss biologic  18 plausibility, and the reason is -- I said  19 before one could make the case of not even  20 performing a Bradford Hill analysis, but for  21 the sake of what other experts did, I went  22 through strength of association, consistency  23 and dose response.  24 And with a lack of strength of  25 association, with a lack of consistency</p>	<p style="text-align: right;">Page 180</p> <p>1 epidemiologic studies that looked at  2 different subtypes.  3 Q. And serous cancers were more  4 associated at a higher rate than other  5 ovarian cancers, correct?  6 A. It depends on which study we're  7 looking at. We'd have to go through all of  8 them.  9 Q. Okay. But would it -- you  10 didn't do that for the purposes of -- you  11 didn't look at whether or not the evidence --  12 there was evidence of specificity to -- for  13 example, epithelial ovarian cancer as opposed  14 to other kinds of cancers?  15 A. That's not --  16 MS. MILLER: Objection.  17 THE WITNESS: That's not  18 exactly what Bradford Hill is talking  19 about when talking about specificity.  20 QUESTIONS BY MR. TISI:  21 Q. Okay.  22 A. The term "specificity" is  23 referred -- the term "specificity" is talking  24 about a specific exposure causing a certain  25 disease, and there are certain diseases that</p>
<p style="text-align: right;">Page 179</p> <p>1 between studies and with a lack of dose  2 response, biologic plausibility doesn't  3 matter because there's no causal association  4 between talcum powder and ovarian cancer  5 based on the medical literature.  6 Q. So let me ask you this: Is the  7 issue of specificity important?  8 For example, wouldn't it be  9 important to consider whether or not the  10 studies that did show an association were  11 specific to a particular type of cancer and  12 not others? Because that would -- that  13 question would argue against the issue of  14 recall bias, for example.  15 A. You asked several questions  16 there, so if you could just break that down,  17 it would be helpful.  18 Q. I'll break it down.  19 Wouldn't it be important to  20 consider the issue of specificity?  21 You know that many of these  22 studies broke down their analysis -- tried to  23 break down their analysis by subtype of  24 ovarian cancer, correct?  25 A. There were several</p>	<p style="text-align: right;">Page 181</p> <p>1 have lots of things that can cause them.  2 But if there is one disease  3 that only one exposure causes, then that's  4 what specificity means. Not specificity in  5 the different type of ovarian cancer.  6 Q. So you don't think it's  7 relevant to look at whether or not a  8 association is correlated more specifically  9 with the type of ovarian cancer as opposed to  10 ovarian cancer generally for the purposes of  11 trying to figure out whether or not there  12 really was bias in these studies?  13 MS. MILLER: Objection.  14 THE WITNESS: I don't even  15 understand what you just asked me.  16 QUESTIONS BY MR. TISI:  17 Q. Okay. You didn't look at --  18 you didn't look at analogy, did you?  19 MS. MILLER: Objection.  20 THE WITNESS: Analogy, again,  21 is -- you'd have to look at something  22 exactly similar to talc, and there's  23 nothing analogous there that --  24 QUESTIONS BY MR. TISI:  25 Q. But you didn't address it in</p>



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<p style="text-align: right;">Page 182</p> <p>1 your report is my question.  2 A. I did not address it.  3 Q. And you didn't address the  4 specificity factor, correct?  5 A. Again, specificity in this  6 case, as in cases of other diseases where  7 there are a number of potential risk factors,  8 it's not appropriate to look at specificity.  9 Q. Doctor, my question is: You  10 didn't address it in your report at all?  11 MS. MILLER: Please don't  12 interrupt him.  13 THE WITNESS: It's inherent in  14 there.  15 QUESTIONS BY MR. TISI:  16 Q. Okay. It's not addressed  17 specifically in your report, is it?  18 MS. MILLER: Objection.  19 QUESTIONS BY MR. TISI:  20 Q. You didn't say, "I address the  21 specificity factor, and it doesn't apply or  22 it does apply" for the following reasons?  23 MS. MILLER: Objection.  24 THE WITNESS: Again, there is  25 not a line item that says specificity,</p>	<p style="text-align: right;">Page 184</p> <p>1 A. So, first of all, it says  2 "perfectly clearcut."  3 Q. I understand you quoted him,  4 and I'm asking you -- I'm not asking you what  5 he meant because I think it's -- article is  6 pretty clear when he meant.  7 I'm asking you: In the next  8 sentence where you pulled out the word  9 "clearcut," what do you mean?  10 MS. MILLER: Objection.  11 THE WITNESS: One that is  12 beyond that we would attribute to the  13 play of chance.  14 And based on the body of  15 medical evidence and the inconsistency  16 within certain study designs and  17 between certain study designs, the  18 association is not clearcut.  19 QUESTIONS BY MR. TISI:  20 Q. How do you define "clearcut"?  21 In other words, when you say  22 "play of chance," that's a statistical  23 concept.  24 Chance is defined typically by  25 P value, correct, of .05?</p>
<p style="text-align: right;">Page 183</p> <p>1 and because of -- and the reason for  2 that is because there's no strength of  3 association, there's no consistency  4 within studies, and there's no dose  5 response to -- within the studies.  6 And so without those things --  7 QUESTIONS BY MR. TISI:  8 Q. Okay.  9 A. Without those things, the other  10 considerations are -- are -- you can't get  11 there.  12 Q. Okay. Let me go to page 30 of  13 your report. There's a paragraph here that  14 deals with the issue -- it's the seminal --  15 the seminal article paragraph.  16 A. Sure.  17 Q. All right? It says, "Before  18 evaluating causation, study must reveal an  19 association between two variables, preferably  20 clearcut and beyond that -- beyond what we  21 would care to attribute the play of chance.  22 As I discuss further below, the requirement  23 is likely not satisfied here because we are  24 not presented with a clearcut association."  25 How do you define clearcut?</p>	<p style="text-align: right;">Page 185</p> <p>1 A. Chance is defined as a -- about  2 a 1 and 20 chance.  3 Q. Right. A .05 P value, right?  4 A. Statistically, yes.  5 Q. Okay. And so is that what you  6 mean when you say "a clearcut association"?  7 You're talking a statistically  8 significant association, correct?  9 A. I'm not. No, I'm not.  10 MS. MILLER: Objection.  11 QUESTIONS BY MR. TISI:  12 Q. Okay. So what do you mean  13 by -- when you say --  14 A. I wasn't finished.  15 Q. Okay.  16 A. Well, I'm trying to get at what  17 you mean by clearcut association.  18 MS. MILLER: Okay. Objection.  19 Asked and answered.  20 THE WITNESS: One where there  21 is consistency between -- and in this  22 instance, in this specific instance,  23 one where there's consistency between  24 different types of studies and  25 different types of --</p>

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<p style="text-align: right;">Page 186</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. I'm not asking you in this</p> <p>3 case.</p> <p>4 I'm asking you, generally</p> <p>5 speaking, when you say the requirement is not</p> <p>6 satisfied here -- okay, because it's not</p> <p>7 presented with a clearcut association.</p> <p>8 I'm asking you, generally</p> <p>9 speaking, if you're -- if I'm a student at</p> <p>10 Johns Hopkins and I see this sentence and I</p> <p>11 ask you -- raise my hand and say, "Doctor,</p> <p>12 can you tell me what is meant by a clearcut</p> <p>13 association? What is meant by that?" how</p> <p>14 would you -- what would you tell me?</p> <p>15 Without reference to any</p> <p>16 specific case, what is meant by clearcut</p> <p>17 association?</p> <p>18 MS. MILLER: Objection.</p> <p>19 THE WITNESS: I would say it</p> <p>20 depends. It depends on what we're</p> <p>21 looking at, what exposure and outcome</p> <p>22 relationship we're looking at. It</p> <p>23 depends what's available in the</p> <p>24 medical evidence. It depends on how</p> <p>25 the study or the initial work was set</p>	<p style="text-align: right;">Page 188</p> <p>1 study types over a period of time that</p> <p>2 show -- some show something and some show</p> <p>3 another, that's inconsistent, and that --</p> <p>4 Q. What do they show here that</p> <p>5 makes them inconsistent?</p> <p>6 MS. MILLER: Objection. He's</p> <p>7 really -- please let him finish his</p> <p>8 sentences.</p> <p>9 THE WITNESS: Can you be more</p> <p>10 specific?</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Yeah. You just made --</p> <p>13 MS. MILLER: You were in the</p> <p>14 middle of a sentence.</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. You just made the statement,</p> <p>17 "Some show something and some show another,</p> <p>18 that's inconsistent."</p> <p>19 My question is, what: Here --</p> <p>20 what is the "something" you're referring to?</p> <p>21 A. Well, if we're specifically</p> <p>22 talking about the potential causal</p> <p>23 association between talcum powder and ovarian</p> <p>24 cancer, there are hospital-based case-control</p> <p>25 studies that are all not statistically</p>
<p style="text-align: right;">Page 187</p> <p>1 up. It depends on whether or not bias</p> <p>2 and confounding were taken care of.</p> <p>3 It depends on so many factors</p> <p>4 that it makes it impossible to even</p> <p>5 answer that question.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. Would it matter whether or not</p> <p>8 the study was replicated, in other words,</p> <p>9 that there was more than one study?</p> <p>10 A. So sometimes replication can</p> <p>11 help with --</p> <p>12 Q. Is it necessary?</p> <p>13 A. So I was -- wasn't done.</p> <p>14 Q. Okay.</p> <p>15 A. So sometimes replication can be</p> <p>16 helpful.</p> <p>17 Is it necessary? Not</p> <p>18 necessarily, because you could have one very,</p> <p>19 very, very good initial study where you've</p> <p>20 taken care of lots of things like bias and</p> <p>21 confounding and random error and the analysis</p> <p>22 is fine, and so you do come up with, "Hey, we</p> <p>23 think this association is real. Let's do</p> <p>24 further studies."</p> <p>25 But when you look at different</p>	<p style="text-align: right;">Page 189</p> <p>1 significant.</p> <p>2 There are population-based</p> <p>3 case-control studies; some are statistically</p> <p>4 significant, some are not.</p> <p>5 There are cohort studies, four</p> <p>6 of them, all not statistically significant.</p> <p>7 And so when you break down this</p> <p>8 association in trying to look at causality,</p> <p>9 when you break down things -- when you break</p> <p>10 down this by study design, there's a</p> <p>11 difference. There's an inconsistency between</p> <p>12 cohort studies and cases controls. There's</p> <p>13 an inconsistency between population-based</p> <p>14 case controls and hospital-based case</p> <p>15 controls.</p> <p>16 Q. Okay. So if I understand you</p> <p>17 correctly --</p> <p>18 A. And so the association is not</p> <p>19 clearcut.</p> <p>20 Q. Okay. So if I can go to</p> <p>21 page 45 of your report -- I was going to</p> <p>22 discuss this later, but this seems to be a</p> <p>23 perfect time.</p> <p>24 On page 45 you state, "It is</p> <p>25 important to remember, contrary to the</p>

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<p style="text-align: right;">Page 190</p> <p>1 suggestion of plaintiffs' experts, in 2 parentheses, that this criterion" -- and the 3 criterion we're talking about is 4 consistency -- "to weigh in favor finding 5 causal association must be consistency in 6 statistically significant associations." 7 And you have that in bold, 8 correct? 9 A. Are we reading the first 10 sentence? 11 Q. Correct. 12 A. Okay. Can I read it? 13 Q. Sure. 14 A. You want me to read it out 15 loud? 16 Q. No, I just read it. 17 A. I was flipping through, trying 18 to -- 19 Q. That's okay. Let me read it 20 again. 21 You state, "It is important to 22 remember, contrary to the suggestion of 23 several of plaintiffs' experts, that for this 24 criterion to weigh in favor of finding a 25 causal relationship, there must be</p>	<p style="text-align: right;">Page 192</p> <p>1 <b>difficult to prove causality.</b> 2 QUESTIONS BY MR. TISI: 3 Q. So is an underlying 4 principle -- you say it's important to 5 remember here -- that a statistically 6 significant result is inconsistent with a 7 statistically insignificant result? 8 MR. LOCKE: Objection. 9 MS. MILLER: Objection. 10 THE WITNESS: Can you say that 11 again? 12 QUESTIONS BY MR. TISI: 13 Q. Yes. 14 If one study shows a 15 statistically significant result and one a 16 statistically insignificant result, are they 17 by definition inconsistent? 18 MS. MILLER: Objection. 19 THE WITNESS: I think it 20 depends. If you get 20 studies, and 21 10 of them are statistically 22 significant and 10 are not 23 statistically significant, that's 24 inconsistent. 25</p>
<p style="text-align: right;">Page 191</p> <p>1 consistency in statistically significant 2 associations." 3 And you have that in bold, 4 correct? 5 A. That's correct. 6 Q. Okay. And the report that you 7 cite there is -- I'm sorry, you don't cite 8 anything for that. 9 Can you tell me your basis for 10 that -- 11 MS. MILLER: Objection. 12 QUESTIONS BY MR. TISI: 13 Q. -- statement? 14 MS. MILLER: Objection. 15 THE WITNESS: As an 16 epidemiologist, if we are -- if I'm 17 asked to weigh the body of evidence 18 and there is inconsistency in 19 statistical significance, it makes it 20 impossible to conclude a causal 21 relationship between exposure and 22 outcome. 23 <b>Because if you're not showing</b> 24 <b>consistent statistical significance,</b> 25 <b>then that association becomes very</b></p>	<p style="text-align: right;">Page 193</p> <p>1 QUESTIONS BY MR. TISI: 2 Q. Okay. Have you done a 3 meta-analysis? 4 A. I have. 5 Q. Okay. Have you ever published 6 a meta-analysis? 7 A. I have not. 8 Q. Are you a biostatistician? 9 A. I've taken courses in 10 biostatistics. I don't consider myself a 11 biostatistician, but oftentimes there is a 12 link between epidemiology and biostatistics. 13 So I do a lot of my statistical analysis 14 myself. I don't consider myself a 15 biostatistician, though. 16 Q. Okay. Do you hold yourself out 17 to colleagues as a biostatistician or a 18 statistician? 19 MS. MILLER: Objection. Asked 20 and answered. 21 THE WITNESS: Again, I consider 22 myself an epidemiologist, and we do 23 have training in biostatistics, and 24 they're not -- they're oftentimes 25 very, very linked. I don't call</p>

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<p style="text-align: right;">Page 194</p> <p>1 myself a biostatistician.  2 QUESTIONS BY MR. TISI:  3 Q. Okay. By virtue of being --  4 would you agree with me that though there is  5 overlap between the two professions -- you  6 guys need each other, right? -- it is not  7 necessarily the case that a biostatistician  8 is an epidemiologist and an epidemiologist is  9 a biostatistician?  10 MS. MILLER: Objection.  11 MR. LOCKE: Objection.  12 THE WITNESS: That's pretty  13 general. I mean, there are probably  14 people out there that are both.  15 QUESTIONS BY MR. TISI:  16 Q. And there are some that are one  17 and not the other, correct?  18 A. I have no idea. It's not  19 something I think about.  20 Q. Okay. What is the latency of  21 ovarian cancer between something that may  22 cause it and something that -- and the onset  23 of disease?  24 MS. MILLER: Objection.  25 THE WITNESS: I don't think</p>	<p style="text-align: right;">Page 196</p> <p>1 an infection at age 1, and we follow  2 them for 20 years.  3 Sometimes we ask about things  4 and we follow people for an  5 appropriate amount of time, but they  6 may have been exposed to that prior to  7 that. So it really depends.  8 QUESTIONS BY MR. TISI:  9 Q. Now, I asked you a couple of  10 questions before about the role of  11 professional judgment in looking at the  12 Bradford Hill guidelines.  13 Do you remember those  14 questions?  15 A. Not specifically, no.  16 Q. Okay. Well, I'm going to turn  17 to that question now. I told you I'd come  18 back to it, and I'm going to come back to it  19 now.  20 Did you use -- when looking at  21 all of this evidence that you looked at, did  22 you use any degree of professional judgment  23 in analyzing the question of whether or not  24 talcum powder products cause ovarian cancer?  25 A. I don't know what you mean by</p>
<p style="text-align: right;">Page 195</p> <p>1 anybody knows the latency of ovarian  2 cancer and -- first of all, you'd have  3 to not just say something, you'd have  4 to say what risk factor you're talking  5 about. Is it risk factor X, and do we  6 know that, has that been studied?  7 So talking about the latency of  8 ovarian cancer with such generalities,  9 I don't think anybody can answer that.  10 QUESTIONS BY MR. TISI:  11 Q. Well, is that important to  12 consider when looking at cohort studies and  13 to see whether or not they're long enough?  14 MS. MILLER: Objection.  15 THE WITNESS: So that depends.  16 It depends on whether -- certainly it  17 does depend on how long you follow  18 someone in a cohort study, yeah, but  19 also depends on when potentially the  20 exposure could have started.  21 For instance, in cohort studies  22 that I have performed in patients with  23 cystic fibrosis who have had lung  24 transplants, some are born with  25 conditions. Some are -- some acquire</p>	<p style="text-align: right;">Page 197</p> <p>1 "professional judgment."  2 What I did is I reviewed the  3 literature. I read the articles. I looked  4 at how the studies were designed, whether or  5 not they controlled for bias or adjusted for  6 potential confounding, sample size in  7 studies, the differences in population  8 between the case-control studies, the number  9 of people in cohort studies, how long people  10 were followed.  11 So I don't know what you mean  12 by professional judgment, but that's what I  13 did.  14 Q. Well, I mean, you provided a  15 list of people -- you provided a list of  16 things that you did.  17 Is there anything on that list  18 that you think that any of plaintiffs'  19 experts did not do?  20 A. You'd have to get way more  21 specific about that.  22 Q. I'm asking you. Did you -- you  23 reviewed their reports.  24 Is there anything -- any part  25 of you -- did they look at bias, study</p>

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<p>1 design, number of patients enrolled, all 2 those things that you just mentioned? You 3 listed a bunch of them. 4 Can you think of any gap in 5 their report where they didn't consider the 6 things you considered? 7 MS. MILLER: Objection. 8 THE WITNESS: You'd have to 9 show where what we're -- what you're 10 asking me about. 11 QUESTIONS BY MR. TISI: 12 Q. No, I'm not going to do that, 13 Doctor. 14 I'm asking can you think of any 15 as you sit here right now? 16 MS. MILLER: Objection. Asked 17 and answered. 18 THE WITNESS: Without us going 19 through the specifics, I can't answer 20 that general question. 21 QUESTIONS BY MR. TISI: 22 Q. So do you agree that it is 23 well-understood that Hill's postulates are 24 ones in which experts will always apply 25 professional judgment?</p>	<p>1 because it's one of my textbooks. I'm 2 not here to provide opinions on 3 whether or not I think a textbook is 4 authoritative. I'm here to give you 5 my opinion on the medical evidence. 6 (Merlo Exhibit 22 marked for 7 identification.) 8 QUESTIONS BY MR. TISI: 9 Q. Well, you cited a textbook -- 10 okay. Let me ask you this. Let me look at 11 Exhibit 22. 12 Here is a -- it's called 13 Epidemiology, Concepts and Methods. 14 Do you see that, Doctor? I 15 just included the cover page. 16 MS. MILLER: I'm going to 17 object to this exhibit. It is two 18 pages pulled from a book, and the 19 second page ends in the middle of a 20 sentence. 21 MR. TISI: I'm not asking that 22 question. Why don't you -- 23 MS. MILLER: I just don't think 24 it's a proper exhibit. 25 MR. TISI: I know you don't</p>
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<p>1 A. I don't -- what are you 2 referring to? 3 Q. Well, let me ask you this: In 4 your report you refer oftentimes to a 5 textbook by William Oleckno. 6 Do you know that -- 7 A. The textbook? 8 Q. Yeah. 9 A. I do know that textbook. 10 Q. Okay. 11 MS. MILLER: If we're going to 12 move on to a new subject, lunch has 13 been waiting for a while, so maybe -- 14 MR. TISI: Well, I just opened 15 up a can of worms here, so I'm going 16 to just -- give me about five, ten 17 minutes, and we'll get done with this 18 section. 19 QUESTIONS BY MR. TISI: 20 Q. You cited it several times 21 because you find that that is an 22 authoritative textbook in the area of 23 epidemiology? 24 MS. MILLER: Objection. 25 THE WITNESS: I cited it</p>	<p>1 think so. You don't think anything is 2 proper. 3 But I'm going to ask -- why 4 don't you wait until I ask my 5 question, and then we can figure out 6 whether or not I'm doing something 7 improper or not. 8 MS. MILLER: I'm objecting to 9 the exhibit, not to the question. 10 MR. TISI: Okay. That's fine. 11 I'm objecting to your objections 12 because I think they're ridiculous. 13 MS. SHARKO: Please be 14 professional. 15 MR. TISI: Oh, I'm very 16 professional, Counsel, except when 17 somebody is an intrusive as Ms. Miller 18 has been in any deposition I've been 19 involved with. 20 MS. SHARKO: That's so 21 inappropriate. 22 MR. TISI: I know you think it 23 is inappropriate. 24 MR. LOCKE: Objection. I'm 25 objecting to the exhibit as well.</p>

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<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. So there is a paragraph here on</p> <p>3 page 188, and I'm going to ask you whether</p> <p>4 you agree with it or not, and I'm going to</p> <p>5 ask you to read it.</p> <p>6 It says --</p> <p>7 A. So what am I looking at here?</p> <p>8 Q. On page 188, Chapter 7.</p> <p>9 A. No, what is this exhibit?</p> <p>10 Q. It is a -- it is a -- it is a</p> <p>11 page of Chapter 7, Association, Causation in</p> <p>12 Epidemiology.</p> <p>13 There's a chapter from</p> <p>14 Dr. Oleckno's book.</p> <p>15 A. Okay. So I see a photocopy of</p> <p>16 what appears to be the cover of the book.</p> <p>17 Q. The first chapter -- the first</p> <p>18 page of the chapter.</p> <p>19 A. Of Chapter 7.</p> <p>20 Q. And there's a paragraph on</p> <p>21 Bradford Hill. Okay?</p> <p>22 And I'm going to ask you about</p> <p>23 the paragraph that he writes on Bradford</p> <p>24 Hill. It's the only paragraph that he talks</p> <p>25 about Bradford Hill.</p>	<p>1 association, correct? Temporal sequence,</p> <p>2 temporality?</p> <p>3 A. We're talking about that last</p> <p>4 sentence there?</p> <p>5 Q. Yes, correct.</p> <p>6 A. "In the end, the process of</p> <p>7 determining causation is largely subjective</p> <p>8 except for the first guideline, which is</p> <p>9 actually a requirement."</p> <p>10 Q. And the first guideline is</p> <p>11 correct temporal sequence?</p> <p>12 A. I'm not sure what it's</p> <p>13 referring to, but I see "correct temporal</p> <p>14 sequence" right below that.</p> <p>15 Q. All right. Do you disagree</p> <p>16 that the determination of causation is</p> <p>17 largely subjective, if using Hill's</p> <p>18 postulates?</p> <p>19 A. Can you ask that again?</p> <p>20 Q. Yeah.</p> <p>21 Do you believe that the</p> <p>22 ultimate decision on causation requires -- is</p> <p>23 a subjective look at the evidence?</p> <p>24 MS. MILLER: Objection.</p> <p>25 THE WITNESS: I'm not -- I'm</p>
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<p>1 MS. MILLER: Objection. We --</p> <p>2 MR. TISI: That's fine.</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. "On 1965, Sir Bradford Hill,</p> <p>5 professor emeritus at the medical statistics</p> <p>6 with the University of London, delivered a</p> <p>7 landmark address where he outlined nine</p> <p>8 criteria that could be used to determine if</p> <p>9 statistical associations were likely to</p> <p>10 represent causal associations. His reasoning</p> <p>11 built on the earlier work of others such as</p> <p>12 John Stuart Mill, who in 1856 had defined</p> <p>13 several canons from which causal</p> <p>14 relationships could be deduced. Over the</p> <p>15 years, many authors have articulated or</p> <p>16 modified Hill's basic criteria which have</p> <p>17 become known as Hill's postulates. Using</p> <p>18 these as a focal point, the following six</p> <p>19 guidelines should be helpful in deciding</p> <p>20 whether or not statistical associations are</p> <p>21 likely to represent causal associations. In</p> <p>22 the end, the process of determining causation</p> <p>23 is largely subjective except for the first</p> <p>24 guideline, which is actually a requirement."</p> <p>25 And that's temporal</p>	<p>1 sorry, I'm just not understanding what</p> <p>2 you're asking.</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. Okay. Do you agree with the</p> <p>5 sentence that -- the last sentence. "In the</p> <p>6 end, the process of determining causation is</p> <p>7 largely subjective except for the first</p> <p>8 guideline, which is actually a requirement"?</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: I see that</p> <p>11 sentence there, and I see that it</p> <p>12 says, "In the end, the process of</p> <p>13 determining causation is largely</p> <p>14 subjective except for the first</p> <p>15 guideline, which is actually a</p> <p>16 requirement."</p> <p>17 What is the question?</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. My question: Do you agree with</p> <p>20 that sentence?</p> <p>21 A. It's written there.</p> <p>22 Q. Do you agree with it?</p> <p>23 A. I think it depends. I think</p> <p>24 it -- it depends on what we're looking at.</p> <p>25 It depends on the exposure outcome</p>



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<p>1 relationship. It's a very, very general 2 question -- 3 Q. Okay. 4 A. -- and a photocopy of one page 5 in a textbook that I don't have memorized. 6 (Merlo Exhibit 23 marked for 7 identification.) 8 QUESTIONS BY MR. TISI: 9 Q. Well, let's look at exhibit 10 number -- let's look at Exhibit Number 23, 11 which is the textbook by Dr. Gordis. And I 12 do have the whole chapter here, so feel free 13 to thumb through it. 14 MS. MILLER: Is this a good 15 time for lunch? You said it was just 16 five minutes. It's been five minutes. 17 MR. TISI: Okay. 18 MS. MILLER: Do you want to do 19 that after lunch? 20 MR. TISI: I would prefer to 21 finish it now, but if you feel like 22 you're -- you absolutely need to have 23 lunch right now, if the witness does, 24 I'm absolutely okay with that. 25 MS. MILLER: We've been going</p>	<p>1 Q. And Dr. Gordis, again, is 2 the -- was the head of the department for 3 epidemiology at Johns Hopkins, correct? 4 A. You know, I don't remember. I 5 know he taught one of my courses. 6 Q. He's a big deal, isn't he? 7 A. I can't remember if he was the 8 head of the department of epidemiology. 9 Q. He's a big deal. He was well 10 known, a well-known epidemiologist? 11 A. I took his course, I mean, but 12 I don't know what you mean by "big deal." I 13 don't -- 14 Q. You don't think he's -- okay. 15 Do you -- you don't understand what his 16 reputation was in the community? 17 A. Again -- 18 MR. LOCKE: Objection. 19 MS. MILLER: Objection. 20 QUESTIONS BY MR. TISI: 21 Q. Let me ask you -- what you 22 think you're here for, candidly, is not as 23 important to me as you answering my 24 questions. Because what I may think 25 important or you may think important and what</p>
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<p>1 an hour and 40 minutes. That's a long 2 time. 3 What do you think, Susan? 4 MS. SHARKO: Yeah. 5 MR. TISI: It's up to you. I 6 said I'm okay with it. 7 MS. SHARKO: Thank you. 8 VIDEOGRAPHER: All right. The 9 time is 12:18 p.m. We're going off 10 the record. 11 (Off the record at 12:17 p.m.) 12 VIDEOGRAPHER: The time is 13 12:57 p.m., and we're back on the 14 record. 15 QUESTIONS BY MR. TISI: 16 Q. Doctor, before the break I was 17 about to hand you Exhibit Number 23. And 18 these are -- just for the record, I had these 19 kind of preorganized, so we're going to skip 20 exhibits. So you may see me bouncing around 21 a little bit. There's not necessarily a 22 rhyme or reason to that. 23 So this is Exhibit Number 23. 24 This is Chapter 14 from the Gordis textbook. 25 A. Sure.</p>	<p>1 Ms. Miller may think important are different. 2 So I'm going to ask this 3 question: Do you have an understanding of 4 the reputation of Dr. Gordis? 5 MS. MILLER: Objection. 6 MR. LOCKE: Objection. 7 THE WITNESS: And I'll state 8 that I took a course by Dr. Gordis in 9 epidemiology. It was Epidemiology I. 10 And I will state again that I'm 11 not here to give an opinion on whether 12 or not I think Dr. Gordis or anyone 13 has a reputation or a good reputation 14 or a great reputation or whatever. 15 QUESTIONS BY MR. TISI: 16 Q. So you have -- you're agnostic 17 to who Dr. -- Dr. Gordis' qualifications? 18 A. What I can say -- 19 MS. MILLER: Objection. 20 THE WITNESS: I didn't say 21 that. 22 QUESTIONS BY MR. TISI: 23 Q. Okay. So what is your 24 assessment? 25 MS. MILLER: Objection.</p>

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<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. What is your assessment then?</p> <p>3 MS. MILLER: Same objection.</p> <p>4 THE WITNESS: What I can say --</p> <p>5 what I can say is that he was a</p> <p>6 professor of mine. I learned a great</p> <p>7 deal from the class that I took that</p> <p>8 he taught, and he was a member of the</p> <p>9 faculty at Johns Hopkins Bloomberg</p> <p>10 School of Public Health.</p> <p>11 But as far as reputation and</p> <p>12 those things, that's -- I don't have</p> <p>13 an opinion about it.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Do you consider him an</p> <p>16 authority?</p> <p>17 MS. MILLER: Objection.</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. You personally consider him an</p> <p>20 authority?</p> <p>21 MS. MILLER: Objection.</p> <p>22 THE WITNESS: I consider</p> <p>23 Dr. Gordis a professor of mine.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. Well, he was a professor of</p>	<p>1 you have an opinion, I'm entitled to ask it.</p> <p>2 Unless counsel tells you that you can't</p> <p>3 answer it, you have to answer it.</p> <p>4 So my question is: Do you have</p> <p>5 an opinion as to whether or not Dr. -- from</p> <p>6 your perspective, he is an authority in the</p> <p>7 field of epidemiology?</p> <p>8 MS. MILLER: Objection.</p> <p>9 MR. LOCKE: Objection.</p> <p>10 MS. MILLER: I'm going to</p> <p>11 object on multiple grounds, one of</p> <p>12 which is asked and answered.</p> <p>13 THE WITNESS: He was a</p> <p>14 professor of mine who taught a course</p> <p>15 in Epidemiology I, we used his</p> <p>16 textbook as one of the references</p> <p>17 during the class, and I had good</p> <p>18 interactions with him during the</p> <p>19 class. That's what I have to say</p> <p>20 about Dr. Gordis.</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. So let's look at Chapter 14,</p> <p>23 Association to Causation: Deriving</p> <p>24 Inferences From Epidemiologic Studies.</p> <p>25 That's what we're doing here</p>
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<p>1 yours, and so I'm asking you: Do you</p> <p>2 consider him to be an authority in the field</p> <p>3 of epidemiology?</p> <p>4 MS. MILLER: Objection.</p> <p>5 THE WITNESS: Dr. Gordis was an</p> <p>6 epidemiologist. He's since passed.</p> <p>7 And he taught a course that I took,</p> <p>8 and that's that.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. So you don't have any feelings</p> <p>11 about his qualifications one way or the</p> <p>12 other?</p> <p>13 A. It's not something I consider.</p> <p>14 It's not something that I -- he taught me a</p> <p>15 class, and I learned a lot from it.</p> <p>16 Now, whether or not he's an</p> <p>17 authority is -- that's -- I don't have an</p> <p>18 opinion -- I'm not here to give an opinion</p> <p>19 about --</p> <p>20 Q. I didn't ask you whether you</p> <p>21 think you're here to give an opinion about</p> <p>22 that. I'm here to ask you questions, and I'm</p> <p>23 entitled to ask you questions. Okay?</p> <p>24 And so if you -- if you don't</p> <p>25 have an opinion, that's one thing. But if</p>	<p>1 today, right? We're deriving -- we're seeing</p> <p>2 whether or not there's an inference from the</p> <p>3 epidemiologic studies?</p> <p>4 MS. MILLER: Objection.</p> <p>5 THE WITNESS: Can you ask me</p> <p>6 that question --</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. Actually, I don't even need to.</p> <p>9 Let's move on.</p> <p>10 Can you look at the page --</p> <p>11 it's 260, please. Actually, go to page 251.</p> <p>12 A. 251. Got it.</p> <p>13 Q. Do you see on page 251 -- and</p> <p>14 I'm not going to ask you to read it.</p> <p>15 Actually, if you go to page 250 --</p> <p>16 MS. MILLER: I'm sorry, Chris,</p> <p>17 I don't think we got a copy.</p> <p>18 MR. TISI: Oh, I'm sorry.</p> <p>19 That's my bad. Here you go.</p> <p>20 MS. MILLER: Thank you so much.</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. There's a section called</p> <p>23 Evidence for Causal Relationship, and then it</p> <p>24 has guidelines for judging whether an</p> <p>25 observed association is causal. On page 250.</p>

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<p>1 A. 250 now.</p> <p>2 Q. Yeah.</p> <p>3 A. 250. Okay. I got it.</p> <p>4 Q. And see Table 14.1 in those</p> <p>5 lists, the five aspects -- excuse me -- the</p> <p>6 nine aspects of Bradford Hill?</p> <p>7 A. Yeah, let me just look at them</p> <p>8 because there are nine there. I just want to</p> <p>9 make sure that those are the nine Bradford</p> <p>10 Hill criteria.</p> <p>11 MR. LOCKE: Objection to the</p> <p>12 use of this exhibit.</p> <p>13 THE WITNESS: So I see these</p> <p>14 nine -- I see Table 14.1 stating</p> <p>15 "guidelines for judging whether an</p> <p>16 observed association is causal," and I</p> <p>17 see nine lines there.</p> <p>18 But there are some lines that</p> <p>19 are not necessarily those that are --</p> <p>20 those that Bradford Hill spoke about</p> <p>21 in his article.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Okay. So if you go to the</p> <p>24 last -- after discussing the nine that he</p> <p>25 discusses, at the very end it has a</p>	<p>1 information needed for doing so. The</p> <p>2 preceding list should therefore be</p> <p>3 considered -- should therefore be considered</p> <p>4 to be only guidelines that can be of most</p> <p>5 value when coupled with reasoned judgment</p> <p>6 about the entire body of available evidence</p> <p>7 in making decisions about causation."</p> <p>8 Did I read that correctly?</p> <p>9 A. Yes, you did.</p> <p>10 Q. Okay. Do you agree with that</p> <p>11 statement?</p> <p>12 MS. MILLER: Objection.</p> <p>13 MR. LOCKE: Objection.</p> <p>14 THE WITNESS: I mean, there are</p> <p>15 so many statements in there, you'd</p> <p>16 have to ask me specifically if I agree</p> <p>17 or disagree with --</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. Well, do you agree with the</p> <p>20 statement that reasoned judgment is important</p> <p>21 when interpreting epidemiologic evidence?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: I didn't write</p> <p>24 this, and I don't know exactly what</p> <p>25 the definition of reasoned judgment</p>
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<p>1 conclusion.</p> <p>2 A. Who are you referring to,</p> <p>3 Dr. Gordis or --</p> <p>4 Q. Dr. Gordis.</p> <p>5 A. -- Bradford Hill?</p> <p>6 Q. Dr. Gordis. At the conclusion</p> <p>7 on page 260.</p> <p>8 A. So we're going to 260 now?</p> <p>9 Q. Uh-huh.</p> <p>10 A. Okay. 260.</p> <p>11 Q. Right.</p> <p>12 There's a conclusion there,</p> <p>13 right?</p> <p>14 A. I see "conclusion," the word,</p> <p>15 yes.</p> <p>16 Q. Okay. And I'm going to read</p> <p>17 it -- the paragraph in the conclusion and see</p> <p>18 whether you agree with it.</p> <p>19 "Although causal guidelines</p> <p>20 discussed in this chapter are often referred</p> <p>21 to as criteria, the term does not seem</p> <p>22 entirely appropriate. Although it may be a</p> <p>23 desirable goal to place causal inferences on</p> <p>24 a firm quantitative and structural</p> <p>25 foundation, at present we do not have all the</p>	<p>1 in -- that's a very vague term.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Okay.</p> <p>4 A. And it's going to be impossible</p> <p>5 to answer that, because I don't know what the</p> <p>6 definition of reasoned judgment is.</p> <p>7 (Merlo Exhibit 24 marked for</p> <p>8 identification.)</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Okay. That's fine.</p> <p>11 Go to page -- we'll discuss</p> <p>12 this real quickly.</p> <p>13 Oh. On page 2 of your report,</p> <p>14 footnote 1, you refer to a lesson from the</p> <p>15 CDC publication. I'd like to mark that as</p> <p>16 Exhibit Number 24.</p> <p>17 A. Where are we now?</p> <p>18 Q. Page 2 of your report, footnote</p> <p>19 1.</p> <p>20 A. Correct. Yes. I have it.</p> <p>21 Q. It refers to a CDC publication?</p> <p>22 A. That's correct.</p> <p>23 Q. Okay? I marked that as Exhibit</p> <p>24 Number 24.</p> <p>25 I assume that this is something</p>

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<p>1 that you read before you cited it in your 2 report? 3 MR. LOCKE: Objection. 4 THE WITNESS: So this -- 5 this -- 6 QUESTIONS BY MR. TISI: 7 Q. Actually, it's a very simple 8 question: I assume you read it before citing 9 it? 10 A. I did look at this website from 11 the CDC. This definition actually comes out 12 of several textbooks, and the reference from 13 those -- 14 Q. Doctor, I didn't ask you that 15 question. I asked you whether you -- 16 A. I'm giving you an answer. 17 Q. I just asked you whether you 18 read it. 19 A. And so I'm giving you an 20 answer. 21 Where I found this definition 22 was in several textbooks. When I looked back 23 to the reference, it referenced this lesson. 24 Did I read this entire thing? 25 I don't recall. I know that I did look this</p>	<p>1 action based on this science and causal 2 reasoning." 3 Do you see that? 4 A. I do see that. 5 Q. Okay. 6 A. And that's why I put this 7 definition in -- 8 Q. Okay. 9 A. -- when I was defining 10 epidemiology, because I said that it's "the 11 study of the distribution and determinants of 12 health-related states or events in specific 13 populations and the application of this study 14 to control health problems." 15 Q. Right. 16 A. And that's what I was looking 17 for, is a definition -- 18 Q. And it also -- and it also uses 19 the word "causal reasoning." 20 A. If I could just finish -- 21 Q. Well, I understand, but -- 22 A. -- because I'm giving you an 23 answer. 24 Q. You're not -- I asked you about 25 a particular sentence. Okay? I didn't ask</p>
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<p>1 up on the CD's website -- CDC's website and 2 did take this definition from one or the 3 entirety of those -- of those references, and 4 I don't specifically remember where. 5 Q. Okay. You cited it, and so 6 let's go through it. Okay? 7 On page 1 it says, 8 "Epidemiology is just -- is not just a 9 research activity but an integral component 10 of public health providing the foundation for 11 directing practical and appropriate public 12 health action based upon this science and 13 causal reasoning." 14 MS. MILLER: Do you know where 15 he is? 16 THE WITNESS: I'm sorry, where 17 are you? 18 QUESTIONS BY MR. TISI: 19 Q. The last sentence on the first 20 page. 21 I'll read it again. 22 "Epidemiology is not just a research activity 23 but an integral component of public health 24 providing the foundation for directing 25 practical and appropriate public health</p>	<p>1 you why you used it. I didn't ask you -- you 2 need to -- I'm perfectly happy to let you 3 answer the question, but I'm also -- it's 4 also important that you listen to my 5 question. Okay? 6 My question is: Do you agree 7 with the statement that I just read? 8 I didn't ask you why. I didn't 9 ask how. I didn't ask you what you did to do 10 get there. I simply asked you whether you 11 agree with it. 12 MR. LOCKE: Objection. 13 MS. MILLER: Objection. 14 Assuming that was a question 15 and not a speech. I'm -- 16 MR. TISI: It was a speech, 17 actually. 18 MS. MILLER: Oh. I'm objecting 19 to it as a speech. 20 MR. TISI: Fine. 21 QUESTIONS BY MR. TISI: 22 Q. So now I'm going to ask you the 23 question. 24 Do you agree with the sentence 25 that is in the article that you cited?</p>

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<p style="text-align: right;">Page 222</p> <p>1 MS. MILLER: Objection.</p> <p>2 THE WITNESS: I would like to</p> <p>3 preface this by saying I am listening</p> <p>4 to your questions.</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. Okay. So I'm going to ask you</p> <p>7 to listen closer because the answers are not</p> <p>8 answering my question.</p> <p>9 So now let me ask you this</p> <p>10 question --</p> <p>11 MR. LOCKE: Objection.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. -- again, and it's a very</p> <p>14 simple one.</p> <p>15 Do you agree with the following</p> <p>16 statement, quote, "Epidemiology is not just a</p> <p>17 research activity but an integral component</p> <p>18 of public health, providing the foundation</p> <p>19 for directing practical and appropriate</p> <p>20 public health action based on this science</p> <p>21 and causal reasoning, close quote."</p> <p>22 Do you agree with that?</p> <p>23 A. It's a statement that's in</p> <p>24 this -- off the website.</p> <p>25 Q. And do you agree with it?</p>	<p style="text-align: right;">Page 224</p> <p>1 epidemiologist uses the scientific methods of</p> <p>2 descriptive and analytic epidemiology as well</p> <p>3 as experience, epidemiologic judgment and</p> <p>4 understanding of local conditions in</p> <p>5 diagnosing the health of a community and</p> <p>6 proposing appropriate practical and</p> <p>7 acceptable public health interventions to</p> <p>8 control and prevent disease in a community."</p> <p>9 First of all, did I read that</p> <p>10 right?</p> <p>11 A. You did read that correctly off</p> <p>12 the page.</p> <p>13 Q. Does it use the word -- does it</p> <p>14 make the statement that it -- that</p> <p>15 epidemiologists use scientific methods of</p> <p>16 descriptive and analytic epidemiology as well</p> <p>17 as experience and epidemiologic judgment?</p> <p>18 Does it not say that?</p> <p>19 MS. MILLER: Objection.</p> <p>20 THE WITNESS: It says,</p> <p>21 "Similarly, the epidemiologist uses</p> <p>22 the scientific methods of descriptive</p> <p>23 and analytic epidemiology as well as</p> <p>24 experience, epidemiologic judgment and</p> <p>25 understanding of local conditions in</p>
<p style="text-align: right;">Page 223</p> <p>1 A. I mean, there's so many aspects</p> <p>2 to that statement --</p> <p>3 Q. I understand.</p> <p>4 A. -- that make it difficult to</p> <p>5 agree or disagree with. It depends. It --</p> <p>6 Q. Okay.</p> <p>7 A. I didn't write it, so I --</p> <p>8 Q. Now let's go to the end where</p> <p>9 it says, "Application" on the last page</p> <p>10 before the summary.</p> <p>11 Application. Do you see the</p> <p>12 paragraph? Let's see if we can read it</p> <p>13 together.</p> <p>14 "Epidemiology is not just the</p> <p>15 study of," in quotes, "public health in a</p> <p>16 population. It also involves applying the</p> <p>17 knowledge gained by the studies to</p> <p>18 community-based practice. Like the practice</p> <p>19 of medicine, the practice of epidemiology is</p> <p>20 both a science and an art. To make a proper</p> <p>21 diagnosis and to prescribe appropriate</p> <p>22 treatment for a patient, the clinician</p> <p>23 combines medical, scientific knowledge with</p> <p>24 experience, clinical judgment and</p> <p>25 understanding of the patient. Similarly, the</p>	<p style="text-align: right;">Page 225</p> <p>1 diagnosing the health of a community</p> <p>2 and proposing appropriate practical</p> <p>3 and acceptable public health</p> <p>4 interventions to control and prevent</p> <p>5 disease in the community."</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. Do you agree with it?</p> <p>8 A. I mean, in general, that seems</p> <p>9 like a statement that -- that's why we use</p> <p>10 epidemiology.</p> <p>11 Q. Okay.</p> <p>12 A. I didn't write this. There's</p> <p>13 no reference there. There's -- this is a</p> <p>14 very, very general statement.</p> <p>15 Q. Okay. I agree.</p> <p>16 But you cited this particular</p> <p>17 document in your report, and I'm asking you</p> <p>18 about it.</p> <p>19 In fact, you make a lot of</p> <p>20 statements in your report that aren't cited</p> <p>21 either, right?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: You asked several</p> <p>24 questions there.</p> <p>25</p>

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<p style="text-align: right;">Page 226</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. Well, okay. You make a lot of</p> <p>3 statements in your report that aren't cited</p> <p>4 either, don't you?</p> <p>5 We just talked about the</p> <p>6 statistical significance paragraph, the one</p> <p>7 that's important to note. There was not a</p> <p>8 citation there either, right?</p> <p>9 MR. LOCKE: Objection.</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: In that instance</p> <p>12 there was not a citation.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. Okay. So the fact that there's</p> <p>15 no citation, does that make your -- the</p> <p>16 opinion you express in your report invalid?</p> <p>17 A. Not necessarily.</p> <p>18 Q. Okay. So --</p> <p>19 A. But --</p> <p>20 Q. I want to ask you about this</p> <p>21 statement.</p> <p>22 A. I --</p> <p>23 Q. Well, I want to ask you about</p> <p>24 this statement. You answered my question,</p> <p>25 saying that there's no --</p>	<p style="text-align: right;">Page 228</p> <p>1 epidemiology.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Understood. I get it. I get</p> <p>4 it.</p> <p>5 Now I'm asking you: In the</p> <p>6 document that you cited is another statement.</p> <p>7 Do you agree with it or not agree with it?</p> <p>8 MS. MILLER: Objection.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. And if you don't agree with it,</p> <p>11 I want to know why. And if you do agree with</p> <p>12 it, I'm fine with it.</p> <p>13 MS. MILLER: Okay. So what's</p> <p>14 the question? Because I --</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. Do you agree with it, or do you</p> <p>17 don't agree with it?</p> <p>18 MS. MILLER: Objection. Asked</p> <p>19 and answered.</p> <p>20 THE WITNESS: I think in</p> <p>21 general -- it's such a general</p> <p>22 statement that it depends. It depends</p> <p>23 on what we're talking about. It</p> <p>24 depends on what the study is doing.</p> <p>25 It's so general that there's no</p>
<p style="text-align: right;">Page 227</p> <p>1 A. No, I didn't. No, I didn't. I</p> <p>2 didn't finish. And --</p> <p>3 Q. Doctor --</p> <p>4 A. And --</p> <p>5 Q. Do you agree or disagree --</p> <p>6 MS. MILLER: He's literally in</p> <p>7 the middle of a word --</p> <p>8 THE WITNESS: And I would</p> <p>9 appreciate it if you would stop</p> <p>10 interrupting. Just let me finish.</p> <p>11 It's fine.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. Fine. I would appreciate if</p> <p>14 you answer my question.</p> <p>15 Do you agree or disagree with</p> <p>16 the application paragraph in this document?</p> <p>17 MR. LOCKE: Objection.</p> <p>18 THE WITNESS: It's not</p> <p>19 something to agree or disagree with.</p> <p>20 It's from a website that is online.</p> <p>21 I cited this to give a</p> <p>22 definition of what epidemiology is.</p> <p>23 It doesn't mean I agree or disagree</p> <p>24 with the entire thing. I used this as</p> <p>25 a way to get a definition for</p>	<p style="text-align: right;">Page 229</p> <p>1 way to agree or disagree with it.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Okay. Well, I guess the CDC</p> <p>4 would be happy to know that.</p> <p>5 MR. LOCKE: Objection.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. Let's move on to the discussion</p> <p>8 on paragraph -- page 33, footnote 75. And we</p> <p>9 talked about this very briefly, the IPPHS</p> <p>10 study on the primary pulmonary hypertension?</p> <p>11 A. Are you referring to my report?</p> <p>12 Q. Yes.</p> <p>13 A. Okay.</p> <p>14 Q. Page 33?</p> <p>15 A. 33.</p> <p>16 Q. Footnote 75.</p> <p>17 In the footnote you cite a</p> <p>18 study by Abenhaim, appetite suppressants and</p> <p>19 the risk of primary pulmonary hypertension in</p> <p>20 1996, for the proposition for -- where you're</p> <p>21 discussing strength of association, correct?</p> <p>22 A. That's correct.</p> <p>23 Q. All right. And I thought that</p> <p>24 was an interesting example that you took, and</p> <p>25 I want to ask you some questions about that.</p>

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<p>1 You mentioned before that you</p> <p>2 believe that anorexigens, fenfluramine and</p> <p>3 dexfenfluramine, can cause primary pulmonary</p> <p>4 hypertension, correct?</p> <p>5 You remember that testimony?</p> <p>6 MR. LOCKE: Objection.</p> <p>7 MS. MILLER: Objection. I</p> <p>8 don't think that characterizes his</p> <p>9 testimony accurately.</p> <p>10 THE WITNESS: As a clinician,</p> <p>11 when I see patients who have been</p> <p>12 diagnosed with pulmonary hypertension,</p> <p>13 asking about anorexigens is part of my</p> <p>14 clinical evaluation because of studies</p> <p>15 that have looked into the association.</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. Okay. So and I think you</p> <p>18 testified before, and the record will reflect</p> <p>19 what you testified to, but I think you did</p> <p>20 testify before that you believed on balance</p> <p>21 that there is cause and effect there. But</p> <p>22 the record will be what the record is.</p> <p>23 Let me ask you this: Are you</p> <p>24 aware -- first of all, this is a case-control</p> <p>25 study, correct?</p>	<p>1 THE WITNESS: No, we'd have to</p> <p>2 look back through the records.</p> <p>3 (Merlo Exhibit 25 marked for</p> <p>4 identification.)</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. My question to you is this:</p> <p>7 Did you do the same kind of rigorous analysis</p> <p>8 of this study that you did of the studies</p> <p>9 involving talc?</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: My -- the reason</p> <p>12 that I included this study in my</p> <p>13 report was because -- was to -- was to</p> <p>14 highlight a strength of association.</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. I understand.</p> <p>17 A. And an odds ratio of 6.3 that</p> <p>18 actually increases to -- well, I could look</p> <p>19 here -- to 23.1 when the drugs were used for</p> <p>20 more than three months is a high strength of</p> <p>21 association.</p> <p>22 Q. Okay.</p> <p>23 A. So the reason that I included</p> <p>24 it was to make the point that it is very,</p> <p>25 very, very difficult, almost impossible, to</p>
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<p>1 A. It is a case-control study.</p> <p>2 Q. Subject to all the same biases</p> <p>3 that you discussed with respect to the</p> <p>4 case-control studies in this case, correct?</p> <p>5 MS. MILLER: Objection.</p> <p>6 THE WITNESS: So some of the</p> <p>7 biases. But we have to remember that</p> <p>8 this is a medication study, and so the</p> <p>9 medications can be looked at in the</p> <p>10 record, they can be looked as whether</p> <p>11 or not someone's been prescribed them.</p> <p>12 So it is a little bit different</p> <p>13 there in that this is not just</p> <p>14 recalling back, this is -- you can</p> <p>15 look to see whether or not people were</p> <p>16 on medications.</p> <p>17 QUESTIONS BY MR. TISI:</p> <p>18 Q. Do you know whether they did</p> <p>19 that?</p> <p>20 A. I'd have to read the article</p> <p>21 again.</p> <p>22 Q. Okay. Well, you're just</p> <p>23 speculating right now as you're talking?</p> <p>24 MR. LOCKE: Objection.</p> <p>25 MS. MILLER: Objection.</p>	<p>1 explain away an odds ratio of 23.1 by some</p> <p>2 other factor, bias or confounding.</p> <p>3 Q. It's funny because I was</p> <p>4 involved in the litigation involving that,</p> <p>5 and that's exactly what experts like you</p> <p>6 said.</p> <p>7 But we'll go back -- let me go</p> <p>8 back and ask you this question, Doctor.</p> <p>9 MS. MILLER: Objection.</p> <p>10 MR. LOCKE: Objection.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Do you know --</p> <p>13 MS. MILLER: Enough with the</p> <p>14 speeches. "Experts like you"? What</p> <p>15 does that even mean?</p> <p>16 MR. TISI: Experts like you,</p> <p>17 hired by the companies. Experts like</p> <p>18 you.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. Let me ask you --</p> <p>21 MR. LOCKE: Objection.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Let me ask you --</p> <p>24 MS. SHARKO: Please behave the</p> <p>25 way you would in court.</p>

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<p style="text-align: right;">Page 234</p> <p>1 THE WITNESS: So I've never 2 been hired by a company -- 3 QUESTIONS BY MR. TISI: 4 Q. Okay. 5 A. -- to evaluate primary 6 pulmonary hypertension drugs. So I would 7 appreciate you not labeling me as something 8 that I am not. 9 Q. Okay. So let me ask you this, 10 Doctor: Are you aware that there was no -- 11 first of all, are you aware there's no cohort 12 studies involving primary pulmonary 13 hypertension anorexigen use? 14 A. So I'm aware of cohort studies 15 that have followed patients with pulmonary 16 hypertension, but I'm not aware that they 17 looked at exposures over time in cohort 18 studies. 19 Q. Were you aware that there are 20 no other case-control studies; in fact, this 21 is the only one? 22 MR. LOCKE: Objection. 23 THE WITNESS: Again, I would 24 have to review the medical literature 25 to --</p>	<p style="text-align: right;">Page 236</p> <p>1 ratio for you, Dr. Merlo, to say you don't 2 need a second one, it's enough? 3 MS. MILLER: Objection. 4 MR. LOCKE: Objection. 5 THE WITNESS: So, again, I'm 6 going to say it depends. It depends 7 on not only the study design, but I 8 was going to finish with how the study 9 was conducted. But what plans were 10 taken to try to limit bias, what plans 11 were taken in the analysis to try to 12 adjust for potential confounding, and 13 what was done in the analysis. And 14 that -- it depends. It depends on all 15 those things. 16 QUESTIONS BY MR. TISI: 17 Q. Let's go to your report at the 18 end -- the summary paragraph, and we'll go 19 elsewhere. I want to address your opinions 20 about the so-called hierarchy of evidence. 21 A. Sure. 22 Q. On page 46. 23 A. 46, I got it. 24 MS. MILLER: I'm going to 25 object to that speech.</p>
<p style="text-align: right;">Page 235</p> <p>1 QUESTIONS BY MR. TISI: 2 Q. Would it surprise you? 3 A. I'm sorry? 4 Q. Would it surprise you to know 5 that this is not the -- that this is the only 6 one? 7 MS. MILLER: Objection. 8 THE WITNESS: Not necessarily, 9 and I'll tell you why. Because if you 10 have a study that suggests -- that has 11 an odds ratio of 6.3 that goes up to 12 23, as a researcher, I'm not sure 13 another study would need to be done. 14 QUESTIONS BY MR. TISI: 15 Q. Okay. At what point -- what 16 would the odds ratio have to be before you 17 say, we don't need to do a second one? 18 MS. MILLER: Objection. 19 THE WITNESS: It depends. It 20 depends on the study design. It 21 depends on the -- 22 QUESTIONS BY MR. TISI: 23 Q. Say a case-control study, what 24 level would a case-control study have to be 25 in terms of a statistically significant odds</p>	<p style="text-align: right;">Page 237</p> <p>1 QUESTIONS BY MR. TISI: 2 Q. You say -- 3 MR. TISI: No speech. 4 5 QUESTIONS BY MR. TISI: 6 Q. You call it the hierarchy of 7 evidence, right? 8 A. What are you referring to? 9 Q. Okay. "In particular, 10 plaintiffs' experts ignored the hierarchy of 11 evidence in evaluating studies." 12 Do you see that? 13 A. I do see that sentence. 14 Q. Okay. 15 A. Or that partial sentence. 16 Q. I want to talk about that. 17 I take it that you believe that 18 there is a recognized hierarchy of evidence 19 with cohort studies having higher evidentiary 20 values and reliability than case-control 21 studies? 22 MS. MILLER: Objection. Asked 23 and answered before lunch. 24 THE WITNESS: So that's not my 25 belief. It's a belief in epidemiology</p>

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<p style="text-align: right;">Page 238</p> <p>1 that there is a hierarchy of evidence.  2 QUESTIONS BY MR. TISI:  3 Q. Okay. And you also believe  4 that within case-control studies that  5 hospital-based studies are more reliable than  6 population-control studies?  7 MS. MILLER: Objection.  8 THE WITNESS: What are you  9 referring to?  10 QUESTIONS BY MR. TISI:  11 Q. I'm asking -- you say here --  12 MS. MILLER: Can you tell us  13 what page you're on?  14 MR. TISI: 46.  15 MS. MILLER: Thanks.  16 Do you have your report?  17 QUESTIONS BY MR. TISI:  18 Q. In your report you talk about  19 the merits of hospital-based studies  20 versus -- which in your view showed no  21 association, and the case-control studies,  22 some of which showed an association, the  23 population-based ones?  24 MS. MILLER: Is that a  25 question?</p>	<p style="text-align: right;">Page 240</p> <p>1 A. And the reason for that is that  2 there's thought that when a hospital-based  3 case-control study is done, cases and  4 controls think about the past in the same  5 amount; whereas when we have population-based  6 case-control studies, there may be  7 difference -- differences in recall between  8 cases and controls. And that's the  9 definition of recall bias.  10 MR. TISI: Okay. I'm going to  11 move to strike.  12 QUESTIONS BY MR. TISI:  13 Q. My question was in terms of  14 evidentiary value. Do you place  15 hospital-based studies having more -- give  16 them more weight as a study design than  17 population-based case-control study designs?  18 MR. LOCKE: Objection.  19 QUESTIONS BY MR. TISI:  20 Q. For whatever reason. I don't  21 care what the reason is now.  22 MS. MILLER: Objection.  23 THE WITNESS: So I'll say it  24 depends.  25 QUESTIONS BY MR. TISI:</p>
<p style="text-align: right;">Page 239</p> <p>1 MR. TISI: Yes.  2 MS. MILLER: Objection.  3 THE WITNESS: Can you -- can  4 you ask that again? Because I didn't  5 understand that was a question.  6 QUESTIONS BY MR. TISI:  7 Q. Let me ask you directly.  8 In terms of reliability, do you  9 think that hospital-based studies are more  10 reliable than population-based case-control  11 studies?  12 MS. MILLER: Objection.  13 THE WITNESS: I don't know if  14 more reliable -- I don't know if  15 "reliable" is the right term. It's  16 not a term we use in evaluating the  17 literature.  18 But there is some suggestion  19 that hospital-based case-control  20 studies might be less susceptible to  21 recall bias, and recall bias is a  22 tremendous limitation in case-control  23 studies of all kinds.  24 QUESTIONS BY MR. TISI:  25 Q. Okay.</p>	<p style="text-align: right;">Page 241</p> <p>1 Q. Okay.  2 A. And it depends on the -- how  3 the study is put together. It depends on  4 what the study investigators used to tried to  5 limit bias and what the study investigators  6 tried to use to limit confounding.  7 If -- a poorly designed  8 hospital-based study may not be as good as a  9 very well-designed population-based study and  10 vice versa.  11 Q. In terms of -- I'm sorry.  12 A. But if we're talking about  13 serious limitations in case-control studies,  14 recall bias is one of them.  15 And it's an accepted thought  16 that recall bias is less in hospital-based  17 case-control studies when compared to  18 population-based studies.  19 Q. What's your citation for that?  20 A. I would have to look through.  21 I know I talked about it in my report, but I  22 have to -- if you give me a couple seconds,  23 I'll look through that.  24 MS. MILLER: Do you know what  25 page it's on, Counsel?</p>

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<p style="text-align: right;">Page 242</p> <p>1 MR. TISI: Nope.</p> <p>2 MS. MILLER: I do.</p> <p>3 MR. TISI: Good for you.</p> <p>4 MS. MILLER: May I say that to</p> <p>5 cut to the chase?</p> <p>6 MR. TISI: No, I don't want --</p> <p>7 MS. MILLER: You want him to</p> <p>8 read through every page? Okay.</p> <p>9 MR. TISI: I don't want him to</p> <p>10 read every page, but I don't want you</p> <p>11 to coach your witness. Because I</p> <p>12 noticed before that you were circling</p> <p>13 things while he was looking at it, so</p> <p>14 I don't want to do it anymore.</p> <p>15 MR. LOCKE: Objection.</p> <p>16 MS. SHARKO: That's really</p> <p>17 inappropriate --</p> <p>18 MR. TISI: I understand it's --</p> <p>19 MS. SHARKO: -- Mr. Tisi, and</p> <p>20 it's not true.</p> <p>21 MR. TISI: The video will</p> <p>22 demonstrate that it is true.</p> <p>23 MR. LOCKE: It's false. She</p> <p>24 was circling something on the left</p> <p>25 side away from the witness.</p>	<p style="text-align: right;">Page 244</p> <p>1 cases and controls are patients, for</p> <p>2 example, in hospitalized patients."</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. Is there a citation to it?</p> <p>5 A. There is, Schultz and Grimes.</p> <p>6 Q. Okay.</p> <p>7 A. "Where the degree of thinking</p> <p>8 about a possible exposure outcome is likely</p> <p>9 to be at similar levels."</p> <p>10 Q. Okay. All right. So going</p> <p>11 back to the hierarchy of evidence concept --</p> <p>12 because you mentioned that several times</p> <p>13 throughout your report, true?</p> <p>14 A. You've asked me several times</p> <p>15 about it, and I have talked about the</p> <p>16 hierarchy evidence in my report.</p> <p>17 Q. Okay. Well, let's talk about</p> <p>18 the places where you do talk about it.</p> <p>19 You mentioned it in your</p> <p>20 conclusion. We talked about that.</p> <p>21 Can you go to page 27 of your</p> <p>22 report?</p> <p>23 A. Sure.</p> <p>24 Q. At the very bottom of the page</p> <p>25 it says, "While cohort studies have their own</p>
<p style="text-align: right;">Page 243</p> <p>1 MR. TISI: Okay.</p> <p>2 MS. MILLER: To show to Susan.</p> <p>3 MS. SHARKO: With her computer</p> <p>4 open between Ms. Miller and the</p> <p>5 witness.</p> <p>6 MR. TISI: Well, I was accused</p> <p>7 before of kicking under the table,</p> <p>8 which I thought was absolutely</p> <p>9 inappropriate.</p> <p>10 MS. SHARKO: We understand</p> <p>11 that.</p> <p>12 MR. TISI: And incorrect.</p> <p>13 MS. SHARKO: You've mentioned</p> <p>14 that a number of times.</p> <p>15 MR. TISI: And incorrect. And</p> <p>16 incorrect and wrong and</p> <p>17 unprofessional. We're sitting at a</p> <p>18 conference table.</p> <p>19 MS. SHARKO: All right. So</p> <p>20 let's have a truce on the personal</p> <p>21 attacks and just take your deposition.</p> <p>22 MR. TISI: Perfect. Perfect.</p> <p>23 THE WITNESS: So on page 6, the</p> <p>24 last paragraph I say, "Recall bias is</p> <p>25 often less likely to occur when both</p>	<p style="text-align: right;">Page 245</p> <p>1 limitations like any other study design, the</p> <p>2 focused criticism of cohort studies by</p> <p>3 plaintiffs' epidemiologists, even though they</p> <p>4 generally are considered more reliable than</p> <p>5 case-control studies, suggesting a biased</p> <p>6 approach to their analysis."</p> <p>7 Do you see that?</p> <p>8 A. I do.</p> <p>9 Q. Okay. First of all, that's</p> <p>10 another example where you accused our experts</p> <p>11 of being biased, correct?</p> <p>12 MR. LOCKE: Objection.</p> <p>13 MS. MILLER: Objection.</p> <p>14 THE WITNESS: I didn't accuse</p> <p>15 anything. I'm suggesting.</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. Okay. You're suggesting.</p> <p>18 Do you believe that they used a</p> <p>19 biased methodology?</p> <p>20 A. I'm sorry.</p> <p>21 Q. Did you believe that they used</p> <p>22 a biased methodology?</p> <p>23 MS. MILLER: Objection.</p> <p>24 THE WITNESS: What I say here</p> <p>25 is "even though they're generally</p>

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<p>1 considered more reliable than</p> <p>2 case-control studies suggests a biased</p> <p>3 approach to their analysis."</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. Do you believe that they did?</p> <p>6 MS. MILLER: Objection.</p> <p>7 THE WITNESS: I'm just going to</p> <p>8 read what I said.</p> <p>9 MS. MILLER: Asked and</p> <p>10 answered.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. I understand you read what you</p> <p>13 said. This is my opportunity to ask you</p> <p>14 questions about what you wrote. I can read</p> <p>15 what you said, too.</p> <p>16 Okay. So my question to you</p> <p>17 is: Do you believe that they used a biased</p> <p>18 approach --</p> <p>19 MS. MILLER: Objection.</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. -- to their analysis?</p> <p>22 A. What I'm saying is that --</p> <p>23 Q. I'm not asking what you said.</p> <p>24 I'm asking what your opinion is now, Doctor.</p> <p>25 Is your opinion, if I close</p>	<p>1 generally accepted that they are more</p> <p>2 reliable than case-control studies," meaning</p> <p>3 cohort studies, true?</p> <p>4 MR. LOCKE: Objection.</p> <p>5 THE WITNESS: Can you state</p> <p>6 that as a question?</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. Yes.</p> <p>9 Do you state that cohort</p> <p>10 studies here are more reliable than</p> <p>11 case-control studies?</p> <p>12 MS. MILLER: Objection.</p> <p>13 THE WITNESS: So it depends.</p> <p>14 In general, cohort studies, as I</p> <p>15 talked about earlier, when performed</p> <p>16 appropriate -- when designed</p> <p>17 appropriately, when performed</p> <p>18 appropriately, when analyzed</p> <p>19 appropriately, do fall higher up on</p> <p>20 the hierarchy of evidence when</p> <p>21 compared to case-control studies.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. On page 35, you have a whole</p> <p>24 section about the disregard of hierarchy of</p> <p>25 evidence.</p>
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<p>1 this book and we don't read what you said,</p> <p>2 I'm asking you, do you think that they used a</p> <p>3 biased approach in looking at the</p> <p>4 case-control studies and the cohort studies?</p> <p>5 MS. MILLER: He was in the</p> <p>6 middle of answering, and you</p> <p>7 interrupted him to ask the question --</p> <p>8 MR. TISI: No, he was about to</p> <p>9 read me what -- this is what I said.</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. I'm asking you what your</p> <p>12 opinion is.</p> <p>13 A. And my opinion is what I said.</p> <p>14 Q. Okay.</p> <p>15 A. And I'll say again.</p> <p>16 Q. No, you don't need read it</p> <p>17 again. If your opinion is limited to what it</p> <p>18 says here, then that's fine.</p> <p>19 Do you believe -- do you have</p> <p>20 any reason to know that they used -- well,</p> <p>21 strike that. Strike that. We'll let it</p> <p>22 stand.</p> <p>23 Before you discussed the state</p> <p>24 of mind of our experts and their sloppiness,</p> <p>25 their bias approach, you state, "It is</p>	<p>1 Do you see that?</p> <p>2 A. I do see the disregard for</p> <p>3 hierarchy of evidence.</p> <p>4 Q. And you're referring, again, to</p> <p>5 the methodologic flaw of plaintiffs' experts,</p> <p>6 which is the main Section 8 above, correct?</p> <p>7 A. Can you show me what you're</p> <p>8 referring to?</p> <p>9 Q. Yeah.</p> <p>10 Roman Numeral VIII is</p> <p>11 Methodologic Flaws of Plaintiffs' Experts'</p> <p>12 Epidemiology-Based Opinions. That's the</p> <p>13 title of this section?</p> <p>14 A. That's correct.</p> <p>15 Q. And the first criticism you</p> <p>16 have here is disregard for hierarchy of</p> <p>17 evidence, correct?</p> <p>18 A. I see that, disregard for</p> <p>19 hierarchy of evidence.</p> <p>20 Q. Are you saying that the</p> <p>21 plaintiffs' experts disregarded the hierarchy</p> <p>22 of evidence?</p> <p>23 MS. MILLER: Objection.</p> <p>24 THE WITNESS: In general, in</p> <p>25 comparing cohort studies to</p>

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<p style="text-align: right;">Page 250</p> <p>1 case-control studies, they're just not 2 equal. I mean, cohort studies are 3 following subjects -- 4 QUESTIONS BY MR. TISI: 5 Q. Wasn't what I asked. So, 6 Doctor, sorry. I wasn't asking your opinion 7 about case control and cohort. 8 I'm asking you: Did the 9 plaintiffs' experts -- not what your views 10 are. Did, in your opinion, plaintiffs' 11 experts disregard the hierarchy of evidence? 12 MR. LOCKE: Objection. 13 MS. MILLER: Objection. 14 THE WITNESS: So -- and I'll 15 say that in general the hierarchy of 16 evidence does place cohort studies 17 above the case-control studies. And 18 to treat those studies equally in 19 looking at the body of evidence would 20 be disregarding the hierarchy of 21 evidence. 22 QUESTIONS BY MR. TISI: 23 Q. Okay. And you say, "The 24 hierarchy of evidence is well-established in 25 the scientific community." And that's where</p>	<p style="text-align: right;">Page 252</p> <p>1 National Health Medical Research Council is? 2 MR. LOCKE: Objection. 3 THE WITNESS: I do not know who 4 the National Health and Medical 5 Research Council are. 6 QUESTIONS BY MR. TISI: 7 Q. Did you get this document from 8 the defense lawyers or did you find it on 9 your own? 10 A. I found this myself. 11 Q. Okay. Without -- but you don't 12 know who these people are? 13 A. I don't know who a lot of 14 people are that publish things. 15 Q. Well, you don't know what this 16 organization is, do you? 17 A. No, I don't. 18 Q. Okay. So -- but you say 19 here -- the only thing you cite for that is 20 this Australian document. 21 Can you tell me why you didn't 22 go to any of the textbooks that you use at 23 Hopkins to cite this well-established 24 principle? 25 A. No.</p>
<p style="text-align: right;">Page 251</p> <p>1 you cite the National Health and Research 2 Council. 3 And that's that Australian 4 white paper that we talked about before, 5 right? 6 MS. MILLER: Objection. 7 THE WITNESS: I'd have to look 8 at it. 9 (Merlo Exhibit 26 marked for 10 identification.) 11 QUESTIONS BY MR. TISI: 12 Q. Okay. We'll find it. 13 I'll attach this as Exhibit 14 Number 26. This is the paper to which you 15 were referring. 16 A. Yeah, I don't have this 17 memorized, the entirety. 18 Q. I'm not asking you about it. 19 I'm just asking if this is the document you 20 referenced to in your footnote. 21 A. This looks like it. 22 Q. Okay. Before when I asked you 23 about Health Canada, you said you didn't even 24 know who they were. 25 Do you know who the Australian</p>	<p style="text-align: right;">Page 253</p> <p>1 MR. LOCKE: Objection. 2 THE WITNESS: I mean, I could 3 have gone to textbooks, but I didn't. 4 QUESTIONS BY MR. TISI: 5 Q. Well, we will. 6 A. I looked things up. 7 Q. You call this a fundamental 8 principle of epidemiology, if you go to 9 page 46. First sentence, second paragraph of 10 your conclusions. 11 A. The first sentence of the 12 second paragraph? 13 Q. Uh-huh. 14 A. And what was the question? 15 Q. You call it a fundamental 16 principle of epidemiology, right? 17 A. The first sentence of the 18 second paragraph says, "The methodologies 19 used by plaintiffs' experts ignore 20 fundamental principles of epidemiology." 21 Q. In particular, plaintiffs' 22 experts ignore the hierarchy of evidence. 23 A. Yes. 24 Q. That's what you're referring 25 to?</p>

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<p style="text-align: right;">Page 254</p> <p>1 A. Yes.</p> <p>2 Q. Okay. So in your whole report,</p> <p>3 the only thing you cited was this Australian</p> <p>4 document, which we've marked as Exhibit</p> <p>5 Number 26, on this fundamental principle,</p> <p>6 right?</p> <p>7 MR. LOCKE: Objection.</p> <p>8 MS. MILLER: Objection.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Because I don't see any other</p> <p>11 citation in any other place other than this</p> <p>12 Australian document from the organization you</p> <p>13 know who they are.</p> <p>14 A. That's the citation I used. I</p> <p>15 teach about this in class. I've been taught</p> <p>16 about it in class.</p> <p>17 Q. Okay.</p> <p>18 A. You're welcome to take my class</p> <p>19 and see the slides.</p> <p>20 Q. I think I'm gonna.</p> <p>21 Putting aside your concern</p> <p>22 about how the experts weighed the talc</p> <p>23 studies, you believe that the cohort design</p> <p>24 is the best for measuring ovarian cancer?</p> <p>25 MS. MILLER: Objection.</p>	<p style="text-align: right;">Page 256</p> <p>1 A. So I wasn't -- I wasn't</p> <p>2 involved in any of the design of the cohort</p> <p>3 studies, but one of the beauties of a cohort</p> <p>4 study is you actually don't need that.</p> <p>5 Q. Okay.</p> <p>6 A. And what you do is you follow</p> <p>7 patients over time, and sometimes things come</p> <p>8 up. And you might add a questionnaire in and</p> <p>9 then follow because you have a large group of</p> <p>10 people that you're following over time. You</p> <p>11 have a time zero with some measurement, and</p> <p>12 then an outcome that develops. And that's --</p> <p>13 that's the purpose of a cohort study --</p> <p>14 Q. How long --</p> <p>15 A. -- that you don't need to have</p> <p>16 one hypothesis.</p> <p>17 Q. How large would a study -- have</p> <p>18 you done any power calculations to determine</p> <p>19 how large a study would have to be in order</p> <p>20 to accurately collect information that would</p> <p>21 be useful in determining where there's</p> <p>22 association?</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: I don't</p> <p>25 understand your question. It doesn't</p>
<p style="text-align: right;">Page 255</p> <p>1 THE WITNESS: Again, it</p> <p>2 depends. It depends on the -- how the</p> <p>3 study is set up. It depends on</p> <p>4 what -- it depends on how long someone</p> <p>5 is followed. It depends on the study</p> <p>6 population being looked at. It</p> <p>7 depends on what potential bias was --</p> <p>8 tried to -- it depends on the</p> <p>9 investigators planning to try to limit</p> <p>10 bias. It depends on the plan to</p> <p>11 adjust for potential confounders.</p> <p>12 So it depends. It's too</p> <p>13 general to answer.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Do you know whether or not any</p> <p>16 of the cohort studies had, as one of its</p> <p>17 primary focuses at the initiation of this</p> <p>18 study, assessing whether or not talc causes</p> <p>19 ovarian cancer?</p> <p>20 A. Can you ask that again?</p> <p>21 Q. Yes.</p> <p>22 Do you know whether or not one</p> <p>23 of the hypotheses that was considered at the</p> <p>24 inception of any of these cohort studies was</p> <p>25 that talc could cause ovarian cancer?</p>	<p style="text-align: right;">Page 257</p> <p>1 make sense.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. How large? How large would a</p> <p>4 study have to be?</p> <p>5 How many patients would have to</p> <p>6 be enrolled in a cohort study in order to get</p> <p>7 good information about whether or not talc is</p> <p>8 associated with ovarian cancer?</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: So it depends.</p> <p>11 It depends on the study. It depends</p> <p>12 on the study population.</p> <p>13 If you're looking at younger</p> <p>14 women, it may take -- there may be --</p> <p>15 you may need a larger study</p> <p>16 population. If you're looking at</p> <p>17 women, say, in their 50s, you need a</p> <p>18 smaller population.</p> <p>19 It's all going to depend on</p> <p>20 the -- on the incidence of disease in</p> <p>21 the study population.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Did you look at that?</p> <p>24 A. I did.</p> <p>25 Q. Okay. How long would the study</p>

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<p style="text-align: right;">Page 258</p> <p>1 have to be?</p> <p>2 A. It depends. It depends on</p> <p>3 the -- it depends on the population. It</p> <p>4 depends on what the incidence of disease in</p> <p>5 that population is.</p> <p>6 Q. And how long -- how long do you</p> <p>7 think it would have to be for a cohort study</p> <p>8 to detect ovarian cancer in women?</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: Well, then I'm</p> <p>11 going to have to say it depends.</p> <p>12 Because in all women, that will --</p> <p>13 you'd need a very different number</p> <p>14 than in looking at, say, women who are</p> <p>15 55 to 65, because the incidence of</p> <p>16 disease is very different among</p> <p>17 different age populations.</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. Okay. So in women 55 to 65,</p> <p>20 did you independently assess how large a</p> <p>21 study would have to be?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: I looked at power</p> <p>24 and sample size calculation under</p> <p>25 various assumptions, and those</p>	<p style="text-align: right;">Page 260</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. I'm not saying anything.</p> <p>3 What page are you looking at,</p> <p>4 Doctor?</p> <p>5 A. Well, this might not be -- 38.</p> <p>6 So 38, page 38, paragraph 1, where it says,</p> <p>7 "She relies on commentary by Narod, who</p> <p>8 states that the lack of significant overall</p> <p>9 association between ever talc use and ovarian</p> <p>10 cancer in the cohort studies may be due to</p> <p>11 the fact that despite the large size of the</p> <p>12 cohorts, the studies were not adequately</p> <p>13 powered to detect a relative risk of</p> <p>14 approximately 1.2."</p> <p>15 Q. Right.</p> <p>16 A. "But this commentary rests on</p> <p>17 sample size calculations with certain</p> <p>18 assumptions regarding the risk of ovarian</p> <p>19 cancer, including the same incidence rate</p> <p>20 issue that undermines Dr. McTiernan's</p> <p>21 critique. When the actual incidence rate of</p> <p>22 ovarian cancer in the cohort studies is taken</p> <p>23 into account, it decreases the study sample</p> <p>24 size needed to the sample size reported in</p> <p>25 the relevant cohort studies."</p>
<p style="text-align: right;">Page 259</p> <p>1 assumptions utilized the incidence of</p> <p>2 disease and the time to follow someone</p> <p>3 with varying times and varying</p> <p>4 incidence of disease.</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. So how large would a study have</p> <p>7 to be in women age 50 to 55 to detect an</p> <p>8 association between talc and ovarian cancer?</p> <p>9 A. So I used 55 to 65 as an</p> <p>10 example just talking right here. I don't</p> <p>11 specifically remember right now the incidence</p> <p>12 of ovarian cancer in someone who is 55 to 60.</p> <p>13 I know that there are ranges,</p> <p>14 and those ranges are available on the</p> <p>15 Internet to look at incidence of disease</p> <p>16 based on age, and I used some of those ranges</p> <p>17 and some of those incidences.</p> <p>18 Q. Did you do calculations?</p> <p>19 A. I did calculations.</p> <p>20 Q. Where are they?</p> <p>21 A. They're in my report.</p> <p>22 Q. Where are they?</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: Give me a couple</p> <p>25 of seconds to find it.</p>	<p style="text-align: right;">Page 261</p> <p>1 Q. I understood. I read that.</p> <p>2 Where is your calculation for</p> <p>3 that?</p> <p>4 Did you -- it says when -- the</p> <p>5 last sentence says, "When the actual</p> <p>6 incidence rates of ovarian cancer in the</p> <p>7 cohort studies is taken into account, it</p> <p>8 decreases the study sample size."</p> <p>9 You did the calculation to make</p> <p>10 that conclusion, and I don't see it in your</p> <p>11 report.</p> <p>12 Can you tell me where it is?</p> <p>13 A. I did it on a computer, and it</p> <p>14 gave me a sample size that was similar to</p> <p>15 what was reported in the relative cohort</p> <p>16 studies when you use an incidence of ovarian</p> <p>17 cancer that's similar to the incidence rates</p> <p>18 of the population that was being studied.</p> <p>19 Q. You did it on a computer? It's</p> <p>20 not in your report.</p> <p>21 MS. MILLER: Yes, it is.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Well, tell me where it is.</p> <p>24 MR. TISI: I'm not asking</p> <p>25 counsel; I'm asking the witness.</p>

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<p>1 MS. MILLER: Well, we can sit 2 and he can look for it, or I can tell 3 you where it is. 4 MR. TISI: It's funny how that 5 happens. When I ask him about a 6 specific sentence, you want him to 7 read the whole report. 8 MS. MILLER: No, that's not -- 9 no, that's exactly the opposite of 10 what I was saying. I said if you want 11 him to read the whole report, you can. 12 I also know where it is. 13 MR. TISI: No, that's -- it 14 depends on the question. 15 MS. SHARKO: Well, being nice 16 doesn't work, unfortunately. 17 MS. MILLER: Yeah, I'm trying 18 to be nice. That's the irony. 19 MR. TISI: You don't -- fine. 20 MS. MILLER: Do you want to 21 finish that sentence? 22 MR. TISI: Yes. 23 MS. MILLER: Go ahead. 24 MR. TISI: Your conduct during 25 the course of these depositions has</p>	<p>1 comparing participants exposed to talc to 2 participants not exposed to talc, I 3 calculated that the incidence of ovarian 4 cancer in the overall number of study 5 participants was sufficient to detect the 6 true risk of ovarian cancer of 1.25 with a 7 power of 99, 99 percent." 8 Q. So what would the number have 9 to be in order to be -- what was your number? 10 That's what I wanted to know. 11 A. I would have to look at my 12 computer again. I just know it's sufficient. 13 Q. Okay. But you didn't put in 14 your report what the number would have to be 15 to -- so I can't ask you that question, and 16 you don't know it here right now, do you? 17 MR. LOCKE: Objection. 18 THE WITNESS: The number is 19 over the number of participants 20 included in those studies. 21 QUESTIONS BY MR. TISI: 22 Q. Okay. 23 A. And that means that there's 24 only a 1 percent chance of being incorrect -- 25 Q. Okay.</p>
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<p>1 been anything but nice. 2 MR. LOCKE: Objection. 3 MR. TISI: If you really want 4 it to be put on the record, that's 5 what I was going to say. 6 To honor Susan's request, I was 7 going to forebear from that, but you 8 asked. 9 MS. SHARKO: Mr. Tisi, really. 10 THE WITNESS: So just give me a 11 couple seconds. I'll find it. 12 Okay. So I think I found 13 another instance where I described 14 that sample size would be adequate. 15 QUESTIONS BY MR. TISI: 16 Q. Okay. Where is that? 17 A. It's at page 37. 18 Q. Which paragraph? 19 A. Third paragraph. 20 Q. Okay. 21 A. And then halfway down that 22 paragraph it says, "Specifically using the 23 Berge study meta-analysis of cohort studies, 24 which concluded that combined cohort studies 25 yielded no risk of ovarian cancer when</p>	<p>1 A. -- if, in fact, there is no 2 difference in folks who haven't been 3 exposed -- or unexposed to talcum powder. 4 Q. Now, getting back to the -- 5 this fundamental principle of epidemiology 6 that there's this hierarchy of evidence, you 7 know that the current view in epidemiology, 8 in fact, a view that's been for a while, has 9 been that case control and epidemiologic case 10 control and cohort studies are looked at 11 together -- 12 MR. LOCKE: Objection. 13 QUESTIONS BY MR. TISI: 14 Q. -- if they exist together, 15 right? 16 MS. MILLER: Objection. 17 THE WITNESS: I don't 18 understand the question. You have to 19 ask it again. 20 QUESTIONS BY MR. TISI: 21 Q. Well, let's look at the Gordis 22 textbook again. Exhibit Number 23. 23 Can you look at Exhibit 23 24 again, Doctor? 25 MS. MILLER: Is that the</p>

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<p>1 Chapter 14?</p> <p>2 MR. TISI: Yeah.</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. Can you go to page 256? You</p> <p>5 use it as an example -- 255, excuse me. Oh,</p> <p>6 I'm sorry. 257, please.</p> <p>7 He uses as an exam -- and feel</p> <p>8 free to look at if you wish. He uses an</p> <p>9 example, the process for using evidence in</p> <p>10 developing recommendations, effectiveness of</p> <p>11 prenatal interventions. He's giving a</p> <p>12 causation approach here.</p> <p>13 The top here is categorizing</p> <p>14 the evidence by quality and source, and</p> <p>15 stage 2 is using the guidelines of evidence</p> <p>16 of causal relationship, and those would be</p> <p>17 the Bradford Hill criteria.</p> <p>18 Do you see that?</p> <p>19 A. I see this table and I see a --</p> <p>20 something that says, stage 1, categorizing</p> <p>21 the evidence by the quality of its source.</p> <p>22 I see stage 2, guidelines with</p> <p>23 some -- what Dr. Gordis calls criteria, some</p> <p>24 of which are some Bradford Hill</p> <p>25 considerations.</p>	<p>1 is?</p> <p>2 A. No.</p> <p>3 Q. You don't know who he is?</p> <p>4 A. I have no idea.</p> <p>5 Q. Okay. Do you know he's written</p> <p>6 a textbook on epidemiology?</p> <p>7 A. I don't know his textbook, no.</p> <p>8 (Merlo Exhibit 27 marked for</p> <p>9 identification.)</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. Okay. So I'm going to show you</p> <p>12 and ask whether you agree with it. It's a</p> <p>13 textbook on case-control studies.</p> <p>14 Chapter 8. Did you read -- by</p> <p>15 the way, did you read Dr. Ballman's</p> <p>16 testimony?</p> <p>17 A. I did.</p> <p>18 Q. You did.</p> <p>19 So you saw a discussion of</p> <p>20 Dr. Rothman, right?</p> <p>21 A. Yes, but I don't know who</p> <p>22 Dr. Rothman is.</p> <p>23 Q. Okay. Spent a lot of time</p> <p>24 talking about Dr. Rothman.</p> <p>25 Let me ask you this --</p>
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<p>1 Q. Okay. Now, let's look at the</p> <p>2 quality of evidence, because that's what</p> <p>3 we're talking about here, right?</p> <p>4 Number 1 is trials, and we</p> <p>5 talked about those before. Those would be</p> <p>6 kind of the human experimental trials, the</p> <p>7 placebo-control kind of trials, right?</p> <p>8 A. Usually trials are either</p> <p>9 randomized, double-blinded, placebo-control</p> <p>10 trials, or randomized, not blinded, or</p> <p>11 nonrandomized but clinical trials where an</p> <p>12 intervention is done.</p> <p>13 Q. Okay. And the second category</p> <p>14 he has here is cohort or case-control</p> <p>15 studies.</p> <p>16 Do you see that?</p> <p>17 A. I do see that line that says</p> <p>18 "cohort or case-control studies."</p> <p>19 Q. He doesn't say cohort and then</p> <p>20 case-control studies, does he?</p> <p>21 A. He doesn't.</p> <p>22 Q. Okay.</p> <p>23 A. They're both observational</p> <p>24 studies.</p> <p>25 Q. Do you know who Kenneth Rothman</p>	<p>1 MS. MILLER: I'm sorry,</p> <p>2 Mr. Tisi, can we have copies as well?</p> <p>3 MR. TISI: Oh, I'm sorry. That</p> <p>4 was an error. Here you go.</p> <p>5 MS. MILLER: Thank you so much.</p> <p>6 MR. TISI: You're so welcome.</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. Second sentence in the</p> <p>9 textbook -- second paragraph. It's on --</p> <p>10 this is on -- this chapter is entitled</p> <p>11 "Case-Control Studies," right?</p> <p>12 A. This chapter, Chapter 8, called</p> <p>13 "Case-Control Studies."</p> <p>14 Q. The second paragraph begins</p> <p>15 with the sentence, "Conventional wisdom about</p> <p>16 case-control studies is that they do not</p> <p>17 yield estimates of effect that are valid</p> <p>18 measures obtained from cohort studies. This</p> <p>19 thinking may reflect common misunderstandings</p> <p>20 in the conceptualizing of case-control</p> <p>21 studies, which will be clarified later."</p> <p>22 Do you see that?</p> <p>23 A. I do see that.</p> <p>24 Q. Do you agree with that?</p> <p>25 MS. MILLER: Objection.</p>

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<p style="text-align: right;">Page 270</p> <p>1 THE WITNESS: This is a very, 2 very, very vague statement. 3 QUESTIONS BY MR. TISI: 4 Q. Okay. 5 A. And I'm going to have to say it 6 depends. It depends on who's thinking about 7 it. It depends on the quality of the 8 case-control study. It depends on the 9 quality of the cohort study. It depends on 10 so many things that I can't even agree nor 11 disagree with it. 12 (Merlo Exhibit 28 marked for 13 identification.) 14 QUESTIONS BY MR. TISI: 15 Q. Okay. Let me show you another 16 article by Dr. Rothman, Exhibit Number 28. 17 This is a review article 18 entitled "Six Persistent Misconceptions." 19 Do you see that? 20 A. I do. 21 Q. Have you seen this before? 22 A. Yes. 23 Q. Okay. Can you read 24 misconception number 1? 25 MS. MILLER: Objection.</p>	<p style="text-align: right;">Page 272</p> <p>1 that, Doctor? I mean, honestly, I'm pulling 2 up book chapters, published articles. You 3 pulled up a white paper from Australia. 4 How do I check and ask you, 5 other than your say-so, as to what the 6 general acceptance is in the -- in the 7 epidemiologic community, other than you just 8 saying it? 9 MS. MILLER: Objection. 10 MR. LOCKE: Objection. 11 THE WITNESS: You can take a 12 class in epidemiology. 13 QUESTIONS BY MR. TISI: 14 Q. I don't think I'm going to take 15 your class. 16 A. Well, I didn't say my class. 17 You can take any class. 18 Q. I'm reading the textbooks, and 19 they don't say what you say. 20 MS. MILLER: Objection. 21 MR. LOCKE: Objection. 22 (Merlo Exhibit 29 marked for 23 identification.) 24 QUESTIONS BY MR. TISI: 25 Q. I'm going to show you another</p>
<p style="text-align: right;">Page 271</p> <p>1 THE WITNESS: Misconception 1, 2 "There is a hierarchy of study 3 designs. Randomized trials provide 4 the greatest validity, followed by 5 cohort studies, with case-control 6 studies being least reliable." 7 QUESTIONS BY MR. TISI: 8 Q. You are -- studying for your 9 support of this general -- this general 10 proposition, you're citing that Australian -- 11 that Australian white paper, right? 12 MR. LOCKE: Objection. 13 QUESTIONS BY MR. TISI: 14 Q. You didn't study any published 15 literature. You didn't cite textbooks, 16 published literature, nothing? 17 MR. LOCKE: Objection. 18 MS. MILLER: Objection. 19 THE WITNESS: I'm citing -- I'm 20 citing that article, but I'm also 21 referencing my experience in 22 epidemiology as well as the general 23 sense among epidemiologists today. 24 QUESTIONS BY MR. TISI: 25 Q. The general -- how do I check</p>	<p style="text-align: right;">Page 273</p> <p>1 one. This is Dr. Rothman who actually was, 2 unlike you, consulted to look at the talc 3 question back in 2000. 4 Almost 20 years ago, right? 5 I'm going to show you that 6 Exhibit Number 29. 7 MS. SHARKO: Can we please just 8 have questions instead of accusatory 9 speeches? 10 MR. TISI: I thought there was 11 only one objector here. 12 QUESTIONS BY MR. TISI: 13 Q. Doctor, I show you Exhibit 14 Number 28, which is entitled "Interpretation 15 of Epidemiologic Studies on Talc and Ovarian 16 Cancer." 17 Have you seen this before? 18 A. Yes. 19 Q. Okay. Have you been shown or 20 have you seen the section on exposure 21 misclassification on page 3? 22 A. I see the -- I see the 23 paragraph underneath exposure 24 misclassification. 25 Q. Now, just to put things in</p>



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<p style="text-align: right;">Page 274</p> <p>1 context, this is November of 2000, this date</p> <p>2 of this report, correct?</p> <p>3 A. That's correct.</p> <p>4 Q. Okay. This is some -- this is</p> <p>5 like halfway, if that, in the timeline of all</p> <p>6 the studies that have been conducted in this</p> <p>7 case from 1982 to 2016?</p> <p>8 MR. LOCKE: Objection.</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: It's November</p> <p>11 of 2000 --</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. Right.</p> <p>14 A. -- and that's when it was</p> <p>15 published.</p> <p>16 Q. So what he's saying here, and</p> <p>17 I'm going to read it for the record, not all</p> <p>18 the study -- "nearly all the studies were</p> <p>19 case-control studies. It is commonly</p> <p>20 believed that the validity of case-control</p> <p>21 studies is worse than cohort studies, but</p> <p>22 this view is mistaken. The validity of the</p> <p>23 study depends on the specifics of the study</p> <p>24 design, the nature of the data and the nature</p> <p>25 of the hypothesis that the study addresses."</p>	<p style="text-align: right;">Page 276</p> <p>1 design, talked about the methodology used in</p> <p>2 the studies and the conclusions reached in</p> <p>3 the study, right? They went through every</p> <p>4 one of them.</p> <p>5 MS. MILLER: Objection.</p> <p>6 MR. LOCKE: Objection.</p> <p>7 MR. TISI: True?</p> <p>8 MS. MILLER: Objection.</p> <p>9 THE WITNESS: You'd have to be</p> <p>10 more specific --</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Well, you reviewed them and you</p> <p>13 made the criticisms.</p> <p>14 So can you tell me one expert</p> <p>15 who -- both plaintiffs' experts who did not</p> <p>16 look at the study design for the</p> <p>17 case-controls and cohorts, who did not look</p> <p>18 at the methodology and who did not look at</p> <p>19 the results?</p> <p>20 MS. MILLER: Objection.</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: You'd have to be</p> <p>23 more specific. If we look at the --</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. No, you'll have to be more</p>
<p style="text-align: right;">Page 275</p> <p>1 Do you see that?</p> <p>2 A. I do see that.</p> <p>3 Q. Do you agree with it or not?</p> <p>4 A. Well, I think I said earlier,</p> <p>5 and I've said it in my report, that the</p> <p>6 hierarchy of evidence is in general. And I</p> <p>7 said that a poorly designed or a poorly</p> <p>8 executed or a poorly analyzed cohort study</p> <p>9 may be less evident than a very, very</p> <p>10 well-designed case control.</p> <p>11 Q. So when -- I'm sorry.</p> <p>12 A. And the same thing for</p> <p>13 randomized control trials.</p> <p>14 But when looking at the</p> <p>15 different study designs, if properly</p> <p>16 designed, if properly conducted, if properly</p> <p>17 analyzed and if properly interpreted, a</p> <p>18 randomized control trial gives you higher</p> <p>19 evidence than a cohort, which gives you</p> <p>20 higher evidence than a case-control, which</p> <p>21 gives you higher evidence than a case series.</p> <p>22 Q. And you --</p> <p>23 A. In general.</p> <p>24 Q. And you saw that plaintiffs'</p> <p>25 experts, each one of them, talked about study</p>	<p style="text-align: right;">Page 277</p> <p>1 specific because you made some bald</p> <p>2 accusations here, and I really need you to be</p> <p>3 specific. I need you to tell me: Did</p> <p>4 plaintiffs' experts -- did plaintiffs'</p> <p>5 experts -- did they do or not do an analysis</p> <p>6 of each study?</p> <p>7 MS. MILLER: Objection.</p> <p>8 MR. LOCKE: Objection.</p> <p>9 THE WITNESS: There were</p> <p>10 summaries of studies, but we'd have to</p> <p>11 go through each expert and go through</p> <p>12 the reports of each one of them to get</p> <p>13 specific about it.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Okay. You disagree with the</p> <p>16 way in which they characterize them, but they</p> <p>17 just didn't simply list the studies, did</p> <p>18 they?</p> <p>19 MS. MILLER: Objection.</p> <p>20 MR. LOCKE: Objection.</p> <p>21 THE WITNESS: I never said I</p> <p>22 disagreed.</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. Okay.</p> <p>25 A. With whatever you're saying.</p>

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<p>1 Q. Okay. All four studies --</p> <p>2 MS. MILLER: Do you want a</p> <p>3 break?</p> <p>4 MR. TISI: If -- he can tell me</p> <p>5 if he wants a break.</p> <p>6 THE WITNESS: I'm okay.</p> <p>7 MR. TISI: He just said he's</p> <p>8 okay.</p> <p>9 MS. MILLER: Do we have a new</p> <p>10 rule in depositions where lawyers</p> <p>11 can't ask for a break?</p> <p>12 MR. TISI: If you want to ask</p> <p>13 for a break, that's fine. If he's --</p> <p>14 you asked him whether he wants a</p> <p>15 break.</p> <p>16 MS. MILLER: This is just</p> <p>17 getting surreal, Susan.</p> <p>18 MR. TISI: It is totally</p> <p>19 getting surreal. You asked him</p> <p>20 whether he wants a break.</p> <p>21 Can you read that back? Can</p> <p>22 you read that back?</p> <p>23 MS. SHARKO: I thought -- are</p> <p>24 we really going to have this kind of</p> <p>25 meltdown over a break, Mr. Tisi?</p>	<p>1 2:00 p.m. We're going off the record.</p> <p>2 (Off the record at 2:00 p.m.)</p> <p>3 VIDEOGRAPHER: Okay. The time</p> <p>4 is 2:11 p.m., and we're back on the</p> <p>5 record.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. Was the talc/ovarian cancer</p> <p>8 hypothesis prespecified in any of the cohort</p> <p>9 studies?</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: I don't know.</p> <p>12 The cohort studies involving the</p> <p>13 Nurses' Health Study, for instance,</p> <p>14 added a questionnaire in 1982.</p> <p>15 And so if one added a</p> <p>16 questionnaire in 1982 asking about</p> <p>17 talc, at that point in the cohort</p> <p>18 study there may have been a hypothesis</p> <p>19 about that. That's why they added</p> <p>20 that -- that's why one might think</p> <p>21 that they added a questionnaire.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. You don't know that because the</p> <p>24 study doesn't say that, does it?</p> <p>25 MS. MILLER: Objection.</p>
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<p>1 MR. TISI: I am totally okay</p> <p>2 with her taking a break if she says "I</p> <p>3 would like to take a break." But</p> <p>4 don't ask the witness whether he wants</p> <p>5 to take a break, because that suggests</p> <p>6 that he should take a break.</p> <p>7 MS. SHARKO: Seriously?</p> <p>8 MR. TISI: That's coaching.</p> <p>9 MS. SHARKO: That's not</p> <p>10 coaching, Mr. Tisi.</p> <p>11 MS. MILLER: Was there a</p> <p>12 question? Was there a question</p> <p>13 pending?</p> <p>14 MR. TISI: It's totally</p> <p>15 coaching.</p> <p>16 Did you need to take a break,</p> <p>17 or do you want to go forward?</p> <p>18 Do you want to take a break?</p> <p>19 MS. MILLER: I would like to</p> <p>20 take a break.</p> <p>21 MS. SHARKO: I want to take a</p> <p>22 break.</p> <p>23 MR. TISI: Perfect. All you</p> <p>24 have to do is ask.</p> <p>25 VIDEOGRAPHER: The time is</p>	<p>1 THE WITNESS: I'd have to</p> <p>2 review the study back -- to look at</p> <p>3 it. I don't have it memorized.</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. How many times in each of these</p> <p>6 cohort studies -- what is the concept of</p> <p>7 exposure classification?</p> <p>8 A. Can you be more specific?</p> <p>9 Q. Yeah.</p> <p>10 What is exposure mis -- is that</p> <p>11 a term of art in epidemiology?</p> <p>12 A. Well, misclassification is a</p> <p>13 term. And you can have misclassification in</p> <p>14 both exposure and both in outcome if --</p> <p>15 Q. I'm asking you about exposure</p> <p>16 misclassification. Actually, I'm using the</p> <p>17 term that Dr. Rothman used.</p> <p>18 By the way, you know, Doctor,</p> <p>19 the journal American Epidemiologists?</p> <p>20 A. I don't.</p> <p>21 Q. Okay. Do you know -- have you</p> <p>22 ever heard of the Ken Rothman Award in</p> <p>23 epidemiology?</p> <p>24 A. I've never heard of that.</p> <p>25 Q. Okay. All right. So</p>

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<p style="text-align: right;">Page 282</p> <p>1 Dr. Rothman and his colleagues talk about</p> <p>2 exposure misclassification in Exhibit</p> <p>3 Number 29.</p> <p>4 Do you know what that concept</p> <p>5 is?</p> <p>6 A. And what page is that on again?</p> <p>7 Q. I'm just asking you what it is.</p> <p>8 I mean, it's in Exhibit 29 he uses the term.</p> <p>9 Do you know what it is?</p> <p>10 A. Well, you're referring to this.</p> <p>11 I haven't read this paragraph yet, but I do</p> <p>12 know what exposure misclassification is.</p> <p>13 Q. Then that's what I want. What</p> <p>14 is exposure misclassification?</p> <p>15 A. Misclassification involving an</p> <p>16 exposure is when either a study subject is</p> <p>17 classified as being exposed when they're not</p> <p>18 exposed or being classified as not exposed</p> <p>19 when they're exposed.</p> <p>20 Q. And exposure misclassification,</p> <p>21 generally speaking, will bias the results</p> <p>22 towards the null, correct?</p> <p>23 A. Not necessarily.</p> <p>24 Q. I didn't say necessarily. I</p> <p>25 said generally speaking.</p>	<p style="text-align: right;">Page 284</p> <p>1 think you said it's the one that biases</p> <p>2 toward the null -- is that a problem with</p> <p>3 cohort studies?</p> <p>4 A. Nondifferential --</p> <p>5 Q. Nondifferential?</p> <p>6 A. -- misclassification --</p> <p>7 Q. Yes.</p> <p>8 A. -- biases toward the null.</p> <p>9 Q. Right.</p> <p>10 Is that a recognized concern</p> <p>11 with cohort studies?</p> <p>12 A. So it depends. It depends if</p> <p>13 there's some reason to believe that those who</p> <p>14 are exposed actually are unexposed, and those</p> <p>15 that are unexposed are being labeled as</p> <p>16 exposed.</p> <p>17 Q. And in the cohort studies on</p> <p>18 talc, would it -- isn't it generally true</p> <p>19 across the cohort studies that women were</p> <p>20 asked about that talc exposure only once?</p> <p>21 A. I would have to review the</p> <p>22 articles again. I don't know that I</p> <p>23 specifically have that memorized.</p> <p>24 Q. Okay. If that were true, would</p> <p>25 there be a danger of exposure</p>
<p style="text-align: right;">Page 283</p> <p>1 Wouldn't that be the case?</p> <p>2 A. No, absolutely not.</p> <p>3 Q. Okay.</p> <p>4 A. And I'll tell you why.</p> <p>5 Q. Please.</p> <p>6 A. Because there are two different</p> <p>7 types of misclassification. One is</p> <p>8 traditionally referred to as differential</p> <p>9 misclassification, and one is traditionally</p> <p>10 referred to as nondifferential</p> <p>11 misclassification.</p> <p>12 Nondifferential</p> <p>13 misclassification can bias the study results</p> <p>14 to the null. Differential misclassification,</p> <p>15 such as that occurs with recall bias, can</p> <p>16 actually bias the result away from the</p> <p>17 null --</p> <p>18 Q. Okay.</p> <p>19 A. -- and give you an overinflated</p> <p>20 estimate of risk.</p> <p>21 Q. Is recall bias an aspect of</p> <p>22 exposure misclassification; do you think?</p> <p>23 A. Absolutely.</p> <p>24 Q. Okay. So exposure</p> <p>25 misclassification that is differential -- I</p>	<p style="text-align: right;">Page 285</p> <p>1 misclassification?</p> <p>2 A. Again, I think it depends. It</p> <p>3 depends on -- it depends on the</p> <p>4 questionnaire. It depends on the time</p> <p>5 between questionnaire and measurement of</p> <p>6 outcome. It depends on whether or not</p> <p>7 there's any aspect of asking about potential</p> <p>8 exposure in the past, and it depends a lot --</p> <p>9 it depends on a lot of things.</p> <p>10 Q. Did you review the Taher draft</p> <p>11 article meta-analysis?</p> <p>12 A. I did review Taher.</p> <p>13 Q. Do you know whether or not</p> <p>14 exposure misclassification was identified as</p> <p>15 a shortcoming in the cohort studies dealing</p> <p>16 with talc?</p> <p>17 A. I would have to look at the</p> <p>18 draft and see what you're referring to.</p> <p>19 Q. No, I'm not asking about the</p> <p>20 draft. I'm asking in the cohort studies</p> <p>21 themselves.</p> <p>22 A. I'm sorry?</p> <p>23 Q. Didn't the authors of the</p> <p>24 cohort studies identify weaknesses in their</p> <p>25 studies?</p>

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<p style="text-align: right;">Page 286</p> <p>1 MS. MILLER: Objection.  2 THE WITNESS: You'd have to be  3 more specific and see which -- what  4 study are we talking about?  5 QUESTIONS BY MR. TISI:  6 Q. Did they identify a concern  7 about a limitation being that there might be  8 recall -- excuse me, might be exposure  9 misclassification, nondifferential  10 misclassification?  11 MS. MILLER: Objection.  12 THE WITNESS: You'd have to  13 point me to the specific article that  14 you're referring to.  15 QUESTIONS BY MR. TISI:  16 Q. You don't know whether or not  17 the authors in any of those studies discussed  18 it?  19 A. There are so many articles  20 here, so many reports, a lot of paper, I  21 don't have things memorized.  22 Q. You --  23 A. If there's certain -- something  24 that you want to ask me about the cohort  25 studies --</p>	<p style="text-align: right;">Page 288</p> <p>1 MS. MILLER: Objection.  2 MR. LOCKE: Objection.  3 THE WITNESS: I'm sorry?  4 QUESTIONS BY MR. TISI:  5 Q. When's the last time you read  6 your report before you came in here today?  7 A. I read it last night.  8 Q. Okay.  9 A. But again, there's a lot of  10 information here, and I don't have things  11 memorized.  12 Q. I agree. I agree.  13 So on page 24 and 25 you  14 discuss -- and 26 you discuss Gates,  15 Houghton, Gonzales and Gertig. I don't see  16 any discussion about the concern of  17 nondifferential misclassification bias.  18 A. Okay.  19 Q. Do you agree?  20 A. Do I agree with what?  21 Q. Did you discuss nondifferential  22 misclassification bias in your discussion of  23 the four cohort studies?  24 A. I discussed the potential for  25 nondifferential misclassification in</p>
<p style="text-align: right;">Page 287</p> <p>1 Q. You put them in your report.  2 Did you address -- did you  3 address in your report, in your discussion of  4 the cohort studies, the concern about a  5 nondifferential misclassification of  6 exposure?  7 A. Can you ask that again?  8 Q. Yes.  9 In your report on your  10 discussion of the -- what you call the four  11 cohort studies, did you discuss the issue of  12 nondifferential misclassification of  13 exposure?  14 MS. MILLER: Objection.  15 THE WITNESS: I would have to  16 look through my report because I don't  17 have that memorized as well.  18 QUESTIONS BY MR. TISI:  19 Q. Well, your discussion of the  20 individual studies are on --  21 A. Be happy to look at that.  22 Q. Yeah. On Houghton page 24 and  23 25.  24 I mean, I assume you read this  25 before you came in here today, right?</p>	<p style="text-align: right;">Page 289</p> <p>1 observational studies in my report.  2 Q. Did you discuss them in the  3 context of the talc studies?  4 A. I didn't.  5 Q. You know that that's a concern  6 that the plaintiffs' experts had when they  7 looked at the case -- excuse me, the cohort  8 studies, that women were asked only one time  9 whether they were exposed to talc and that  10 there was a potential for nondifferential  11 misclassification bias?  12 MR. LOCKE: Objection.  13 MS. MILLER: Objection.  14 QUESTIONS BY MR. TISI:  15 Q. Do you remember that?  16 A. You'd have to show me  17 specifically what you're referring to.  18 Q. You don't remember that that  19 was -- that was a primary focus of each one  20 of these experts?  21 MR. LOCKE: Objection.  22 MS. MILLER: Objection.  23 THE WITNESS: Again, you'd have  24 to show me the specifics because --  25</p>

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<p style="text-align: right;">Page 290</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. Okay. But you don't address</p> <p>3 that in your report?</p> <p>4 MS. MILLER: Objection.</p> <p>5 THE WITNESS: I'm sorry?</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. You don't address that in your</p> <p>8 report with respect to the individual case --</p> <p>9 the individual cohort studies, do you?</p> <p>10 MR. LOCKE: Objection.</p> <p>11 THE WITNESS: Nondifferential</p> <p>12 misclassification is a potential</p> <p>13 limitation of any observational study.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Okay. I asked you whether you</p> <p>16 discussed it in the context of the cohort</p> <p>17 studies.</p> <p>18 MS. MILLER: Objection.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. The four cohort studies on</p> <p>21 talc, did you discuss -- did you even discuss</p> <p>22 that bias?</p> <p>23 I mean, you're sitting here</p> <p>24 telling our -- telling -- under oath telling</p> <p>25 our -- saying that our experts were, you</p>	<p style="text-align: right;">Page 292</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. It is a general statement, and</p> <p>3 I suspect that -- I suspect that the judge</p> <p>4 might look at some of the words used in here</p> <p>5 and agree with me here.</p> <p>6 Pretty strong terms to say that</p> <p>7 somebody was using a -- conducting an</p> <p>8 analysis for the purpose of litigation and</p> <p>9 all the things that you've said. So -- but</p> <p>10 let's put that aside.</p> <p>11 MS. MILLER: Objection.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. Let's put it aside. Put it</p> <p>14 aside.</p> <p>15 MS. MILLER: If that's a</p> <p>16 speech, I'm objecting to it. It</p> <p>17 mischaracterizes --</p> <p>18 MR. TISI: Put it aside.</p> <p>19 MS. MILLER: It</p> <p>20 mischaracterizes his report. If</p> <p>21 you're going to say it, then you're</p> <p>22 going to have to let me object to it.</p> <p>23 If you didn't want to say it --</p> <p>24 MR. TISI: Put it aside.</p> <p>25 MS. MILLER: -- then you</p>
<p style="text-align: right;">Page 291</p> <p>1 know, litigation-driven opinions, that they</p> <p>2 did all kinds of -- did all kinds of things</p> <p>3 that in your view were inappropriate for the</p> <p>4 purposes of litigation.</p> <p>5 I'm asking you: Did you look</p> <p>6 at the issue of recall -- excuse me, of</p> <p>7 nondifferential exposure misclassification</p> <p>8 with respect to the four cohort studies?</p> <p>9 MS. MILLER: Objection.</p> <p>10 MR. LOCKE: Objection.</p> <p>11 THE WITNESS: So I don't know</p> <p>12 what the first part of what you said</p> <p>13 was, whether or not that was a</p> <p>14 question.</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. Well, you are sitting here</p> <p>17 saying that they applied -- you are sitting</p> <p>18 here, and you've been -- made some very --</p> <p>19 used some very strong words in your report</p> <p>20 about the conduct of the plaintiffs' experts.</p> <p>21 Agreed?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: I mean, that's a</p> <p>24 general -- a very general statement,</p> <p>25 the conduct --</p>	<p style="text-align: right;">Page 293</p> <p>1 shouldn't have said it.</p> <p>2 MR. TISI: Put it aside.</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. You didn't discuss -- one of</p> <p>5 your real criticisms is they did not</p> <p>6 account -- our experts did not account for</p> <p>7 recall bias in each of the case-control</p> <p>8 studies, true?</p> <p>9 A. I'm not saying that it wasn't</p> <p>10 accounted for. It's just a known limitation</p> <p>11 of case-control studies, absolutely.</p> <p>12 Q. Okay. Did our experts consider</p> <p>13 recall bias as part of looking at the</p> <p>14 talc-related case-control studies? Did they</p> <p>15 address the issue?</p> <p>16 MS. MILLER: Objection.</p> <p>17 THE WITNESS: Again, I think</p> <p>18 we'd have to look at each specific --</p> <p>19 each specific expert, and if there's a</p> <p>20 part in the expert report that you'd</p> <p>21 like to discuss, I'd like to have it</p> <p>22 in front of me. I don't have these --</p> <p>23 I don't have these --</p> <p>24 MR. TISI: You --</p> <p>25 THE WITNESS: I don't have</p>

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<p style="text-align: right;">Page 294</p> <p>1 these memorized.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Okay. You had an opportunity</p> <p>4 to write your report. There was no page</p> <p>5 limit on it. You could have written a</p> <p>6 thousand-page report if you'd wanted to.</p> <p>7 My question here is: You don't</p> <p>8 really -- you have criticisms of plaintiffs'</p> <p>9 experts generally, but you don't really</p> <p>10 address what they said about each individual</p> <p>11 study, do you?</p> <p>12 MR. LOCKE: Objection.</p> <p>13 MS. MILLER: Objection.</p> <p>14 THE WITNESS: Again, we'd have</p> <p>15 to go through each report --</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. You don't address. I'm not</p> <p>18 asking what they did. I'm asking: In your</p> <p>19 report, you do not address what each expert</p> <p>20 of the plaintiff said about each study, do</p> <p>21 you?</p> <p>22 MS. MILLER: Objection.</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: I'm not sure what</p> <p>25 you're asking me.</p>	<p style="text-align: right;">Page 296</p> <p>1 exposure misclassification. You identified</p> <p>2 it as a potential weakness generally.</p> <p>3 Did you discuss that issue in</p> <p>4 connection with any one of the four cohort</p> <p>5 studies for talc?</p> <p>6 MS. MILLER: Objection.</p> <p>7 THE WITNESS: Misclassification</p> <p>8 is inherently a limitation in any</p> <p>9 study --</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. And did you --</p> <p>12 A. -- case control or cohort</p> <p>13 studies. There are limitations inherent in</p> <p>14 the case-control studies that are in the</p> <p>15 literature. There are inherent limitations</p> <p>16 in the cohort studies that are out there.</p> <p>17 Q. Right.</p> <p>18 And just testified before that</p> <p>19 because of these things, you have to look at</p> <p>20 the design of each study individually, right?</p> <p>21 A better -- I think you said a</p> <p>22 well-designed cohort study is better than a</p> <p>23 well-designed case-control study, right?</p> <p>24 And a poorly-designed cohort</p> <p>25 study may be less valuable than a</p>
<p style="text-align: right;">Page 295</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. Okay. Did each of the</p> <p>3 plaintiffs' experts address the issue of</p> <p>4 recall bias? Was that issue discussed in</p> <p>5 each and every one of their reports?</p> <p>6 MS. MILLER: Objection.</p> <p>7 THE WITNESS: Again, I'd have</p> <p>8 to go through them and --</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Well, I assume you did that</p> <p>11 before today.</p> <p>12 A. And I don't have them</p> <p>13 memorized.</p> <p>14 Q. Okay.</p> <p>15 A. So if you'd like to go through</p> <p>16 them, I'm happy to sit here and we can go</p> <p>17 through each of them.</p> <p>18 Q. You know that's impossible,</p> <p>19 don't you? In seven hours, you know that's</p> <p>20 impossible, which is exactly why you're</p> <p>21 saying that.</p> <p>22 MR. LOCKE: Objection.</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. Let me ask you this, Doctor:</p> <p>25 You are going -- you are asking -- you are --</p>	<p style="text-align: right;">Page 297</p> <p>1 well-designed case-control study, right?</p> <p>2 MR. LOCKE: Objection.</p> <p>3 MS. MILLER: Objection.</p> <p>4 THE WITNESS: It depends.</p> <p>5 Potentially.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. Of course it depends.</p> <p>8 So the question is: Having</p> <p>9 been dependent upon that, it's incumbent upon</p> <p>10 you as a scientist to look at each study for</p> <p>11 the purpose of design, to see whether one is</p> <p>12 well-designed and one isn't, right?</p> <p>13 MS. MILLER: Objection.</p> <p>14 THE WITNESS: Can you ask that</p> <p>15 again?</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. Yes.</p> <p>18 Since epidemiology -- we went</p> <p>19 through the different examples -- requires</p> <p>20 you to not strictly adhere to a hierarchy but</p> <p>21 look at the particular designs of the</p> <p>22 studies, did you do that with respect to each</p> <p>23 one of these studies?</p> <p>24 A. I did.</p> <p>25 Q. Okay. So with regard to the</p>

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<p style="text-align: right;">Page 298</p> <p>1 cohort studies, okay, did you look at 2 individually whether there was a particular 3 concern with these studies on 4 misclassification bias? 5 A. There's always a concern for 6 misclassification. 7 Q. Understood. Theoretically 8 that's true with every one of these cohort 9 studies. 10 But you know each of these 11 studies only asked these women in decades, 12 most cases decades -- I think the Nurses' 13 Health Study was six and a half years -- but 14 one -- only once about talc usage at the 15 beginning -- at or near the beginning of the 16 study, right? 17 MR. LOCKE: Objection. 18 THE WITNESS: We'd have to 19 break -- that's a very generalized 20 question. 21 QUESTIONS BY MR. TISI: 22 Q. Where is it in your report? 23 Where is it in your report? 24 A. I'm sorry. 25 MS. MILLER: Objection.</p>	<p style="text-align: right;">Page 300</p> <p>1 A. The analysis was done during 2 the follow-up period. 3 Q. Which was when? 4 How many decades after they 5 were initially asked? 6 A. Well, it depends on when the 7 patient -- when the study subject was 8 enrolled. 9 I can say that the Gertig 10 study, it was assessed -- the exposure 11 questionnaire was added in 1982, and they 12 were followed for 14 years on average. 13 Q. Right. 14 And in 14 years, isn't it 15 conceivable that somebody could have started 16 using talc, or somebody that who said they 17 were using talc stopped using talc? 18 A. That's certainly possible, but 19 for four studies to show the same 20 nondifferential misclassification, that would 21 be very, very unlikely. 22 Q. Right. 23 And four studies which asked -- 24 asked the question once at the beginning of 25 the study, right?</p>
<p style="text-align: right;">Page 299</p> <p>1 QUESTIONS BY MR. TISI: 2 Q. Where is your discussion in the 3 report about when they were asked about their 4 talc usage in the cohort studies? 5 A. Well, we can go through my 6 report if you'd like to. 7 Q. You just did that, Doctor, and 8 you said it wasn't here. 9 On page 24 and 25, you have a 10 discussion, the Gertig, Gates, Houghton and 11 Gonzalez studies. There is no discussion in 12 here about when they were asked about the 13 talc and how often they were asked. 14 MR. LOCKE: Objection. 15 THE WITNESS: I would have to 16 look back through my report because I 17 do know that in the Gertig study and 18 the Gates study, the questionnaire 19 that asked women about talc exposure 20 was in 1982. 21 QUESTIONS BY MR. TISI: 22 Q. Correct. 23 A. And so that is when they were 24 asked. 25 Q. And when was the analysis done?</p>	<p style="text-align: right;">Page 301</p> <p>1 MS. MILLER: Objection. 2 QUESTIONS BY MR. TISI: 3 Q. They all had the same flaw. 4 You had four flawed studies, didn't you? 5 MS. MILLER: Can we stick with 6 one question at a time? 7 QUESTIONS BY MR. TISI: 8 Q. You had four flawed studies 9 with respect to misclassification bias. They 10 all asked one time at the beginning of the 11 study; true or not true? 12 MR. LOCKE: Objection. 13 MS. MILLER: Objection. 14 THE WITNESS: The Gates and 15 Gertig study did ask women questions 16 about talc in 1982. That was the only 17 time that they were asked about talc 18 usage in those two studies. 19 QUESTIONS BY MR. TISI: 20 Q. What about Houghton? 21 A. In Gertig -- sorry, in -- let 22 me just do Gonzalez first. 23 Gonzalez were asked if they 24 used talc within 12 months prior to 25 enrollment into the study, and so that's</p>



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<p style="text-align: right;">Page 302</p> <p>1 going to depend on when they enrolled in the</p> <p>2 study in between 2003 to 2009. And they were</p> <p>3 followed for six years afterwards.</p> <p>4 Q. And they were never -- just</p> <p>5 while we're talking about that, were they</p> <p>6 ever asked after enrollment, again, whether</p> <p>7 or not they switched to using talc, or people</p> <p>8 who said they were using talc stopped?</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: They were not</p> <p>11 asked again.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. Okay. Houghton?</p> <p>14 A. In Houghton, participants</p> <p>15 were -- completed an annual questionnaire at</p> <p>16 enrollment. And I don't know if I have the</p> <p>17 specific year that the questionnaire was</p> <p>18 asked, because study subject enrolled from</p> <p>19 1993 to 1998 and then were followed --</p> <p>20 Q. How many years?</p> <p>21 A. An average of 12 years.</p> <p>22 Q. Okay. Were they ever asked in</p> <p>23 that 12 years whether some who had been on</p> <p>24 talc went off, or some who were off talc went</p> <p>25 on in those 12 years?</p>	<p style="text-align: right;">Page 304</p> <p>1 study, do you?</p> <p>2 MS. MILLER: Objection. Asked</p> <p>3 and answered like ten times.</p> <p>4 THE WITNESS: I addressed it in</p> <p>5 the context of my report, and inherent</p> <p>6 in any observational study is the</p> <p>7 potential for misclassification.</p> <p>8 QUESTIONS BY MR. TISI:</p> <p>9 Q. You didn't analyze in your</p> <p>10 report whether the cohort studies in talc</p> <p>11 were flawed or limited in reliability by</p> <p>12 misclassification studies, did you?</p> <p>13 MS. MILLER: Objection.</p> <p>14 THE WITNESS: Can you ask that</p> <p>15 again?</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. Yes.</p> <p>18 Other than making the general</p> <p>19 observation, did you analyze in your report</p> <p>20 whether the cohort talc studies were flawed</p> <p>21 or limited in reliability by</p> <p>22 misclassification bias?</p> <p>23 A. So other than saying what I</p> <p>24 said before, that inherent in all</p> <p>25 observational studies, which I talked about</p>
<p style="text-align: right;">Page 303</p> <p>1 A. They weren't.</p> <p>2 Q. Okay. So those were</p> <p>3 limitations on the cohort studies, correct?</p> <p>4 A. They're potential limitations</p> <p>5 of a cohort study.</p> <p>6 Q. And you don't address those in</p> <p>7 your report, do you?</p> <p>8 A. Again, it's inherent in a</p> <p>9 cohort study that there are potential --</p> <p>10 there's potential exposure misclassification.</p> <p>11 Q. I understand.</p> <p>12 Did you address those -- well,</p> <p>13 in cohort studies they can be asked every</p> <p>14 year about their exposures, right? Some do</p> <p>15 that.</p> <p>16 A. And there's still potential for</p> <p>17 misclassification.</p> <p>18 Q. Understood.</p> <p>19 But these particular studies</p> <p>20 were particularly vulnerable to that bias</p> <p>21 because they asked only once at the beginning</p> <p>22 of the studies, true?</p> <p>23 A. Not necessarily, no.</p> <p>24 Q. Okay. But you don't address it</p> <p>25 at all in the context of each individual</p>	<p style="text-align: right;">Page 305</p> <p>1 in my report, misclassification, other than</p> <p>2 that -- that's what I talked about in my</p> <p>3 report.</p> <p>4 Q. Other than that, the answer is</p> <p>5 no, you didn't discuss them in the context of</p> <p>6 the individual studies?</p> <p>7 MS. MILLER: Objection.</p> <p>8 MR. LOCKE: Objection.</p> <p>9 THE WITNESS: But I discussed</p> <p>10 it within my report, which is within</p> <p>11 the context of the individual studies.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. Let's talk about strength of</p> <p>14 the association. We talked about methodology</p> <p>15 generally. Let's talk about strength.</p> <p>16 On page 32 of your report, you</p> <p>17 say -- you have a section called "Lack of</p> <p>18 Strength of Associations."</p> <p>19 Page 32, bottom, Section D.</p> <p>20 A. Lack of Strength of</p> <p>21 Association.</p> <p>22 Q. Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. On page 33, you say, "The</p> <p>25 heart -- the higher the relative risk, the</p>

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<p>1 greater the likelihood that the relationship 2 is causal." 3 A. I see that. 4 Q. You use the term "weak" or 5 "relatively weak" association seen in the 6 talc and ovarian cancer relationship, 7 correct? You call them weak. 8 A. Where are you? 9 Q. For example, the very -- the 10 very last -- the second full paragraph, last 11 three lines up you say, "Relatively weak 12 associations." 13 A. I'm not seeing where you're 14 referring to. 15 Q. Right there. 16 MS. MILLER: It's hard to see 17 upside down. 18 MR. TISI: Well, I can't do it 19 any other way unless you want me to 20 reach over and point at the witness. 21 I said three sentences up from 22 the second paragraph. 23 MS. MILLER: Three second up -- 24 from the bottom of the second 25 paragraph?</p>	<p>1 A. I wrote that in my report. 2 Q. Okay. And you cite a 1982 3 article by Widner. 4 A. That's correct. 5 Q. And on page 46, you state that 6 "Risk ratios between 1.2 and 1.6 are by 7 definition weak associations." 8 That's your conclusion 9 sentence. First sentence, third paragraph 10 down. 11 "This is by definition a weak 12 association." 13 A. That's correct. 14 Q. Okay. Where is that definition 15 written? 16 MS. MILLER: Objection. 17 THE WITNESS: Well, I would 18 have to go back and look at the 19 article that I referenced. 20 QUESTIONS BY MR. TISI: 21 Q. Is that the only -- is that the 22 only article that you can think of? 23 A. It's the only article that 24 comes to mind that I could find, but it's a 25 generally accepted -- generally accepted in</p>
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<p>1 MR. TISI: Yeah. 2 MS. MILLER: Oh, okay. I see 3 it now. I misunderstood you. 4 THE WITNESS: I see that. 5 QUESTIONS BY MR. TISI: 6 Q. And on page 42, you say, "It is 7 generally accepted that risk ratios -- that 8 ratios of risk measures between 1.1 and 2.0 9 represent a weak association between exposure 10 and outcome." 11 A. What page is that on? 12 Q. 42. 13 A. And where is that? 14 Q. I'm sorry. I'm sorry, page 43, 15 second paragraph. "Although there is no 16 universe numeric definition of a strong 17 association between exposure and risk, it is 18 generally accepted that risk -- that ratios 19 of risk measures between 1.1 and 2.0 20 represent a weak association between exposure 21 and outcome." 22 Is that right? 23 Did you say that? 24 A. Did I -- 25 Q. Yes.</p>	<p>1 the epidemiologic community that anything 2 less than 2 is a weak association. 3 Q. Anything less than 2 is weak? 4 A. So, again, it depends, because 5 there are certain studies that may show, that 6 have been designed properly, that bias and 7 confounding aren't a problem, that analysis 8 is great and interpretation is fine where 9 that association, that relative risk, even 10 though it's less than 2 considered weak, that 11 may be -- that may point towards causality 12 between an exposure and an outcome. 13 However, when bias and 14 confounding are potential to be present -- 15 for instance, if we're going to talk about 16 confounding, which I think I should -- 17 Q. I'm asking you about the 18 definition, where, by definition, something 19 less than 2.0 is weak. 20 A. It's a generally accepted -- 21 Q. Generally accepted? 22 A. It's generally accepted in the 23 epidemiology community. 24 (Merlo Exhibit 31 marked for 25 identification.)</p>

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<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. I'm going to show you</p> <p>3 Exhibit Number 31, which is the National</p> <p>4 Cancer Institute statements on ovarian</p> <p>5 cancer.</p> <p>6 Have you seen this before?</p> <p>7 A. No.</p> <p>8 MR. LOCKE: Objection.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Okay. If you look at the</p> <p>11 second page, it talks about factors within --</p> <p>12 "with adequate evidence of increased risk of</p> <p>13 ovarian, fallopian tube and primary</p> <p>14 peritoneal cancers."</p> <p>15 Do you see that?</p> <p>16 A. I see that.</p> <p>17 Q. You see they talk about</p> <p>18 endometriosis.</p> <p>19 MS. MILLER: Can you point me</p> <p>20 to that?</p> <p>21 MR. TISI: Yeah. You see where</p> <p>22 endometriosis is?</p> <p>23 MS. MILLER: No, that's why I'm</p> <p>24 asking you to point --</p> <p>25 MR. TISI: It's on page 3 of</p>	<p>1 magnitude of effect modest with observed</p> <p>2 relative risks of 1.2 to 1.8.</p> <p>3 Q. Do you think the National</p> <p>4 Cancer Institute doesn't understand the --</p> <p>5 doesn't understand the concept of strength of</p> <p>6 association and this generally accepted</p> <p>7 principle that anything under 2.0 is weak?</p> <p>8 MS. MILLER: Objection.</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: So again, I'm not</p> <p>11 here to give an opinion on the</p> <p>12 National Cancer Institute. I don't</p> <p>13 know who put this document together,</p> <p>14 and I did say that it depends. It</p> <p>15 depends on the study.</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. Okay.</p> <p>18 A. But in general, a relative risk</p> <p>19 of -- or an odds ratio of less than 2 is a</p> <p>20 weak association.</p> <p>21 Q. What about obesity and height,</p> <p>22 the next one? It says, based on fair</p> <p>23 evidence -- not even great evidence but fair</p> <p>24 evidence -- obesity and height are associated</p> <p>25 with a modest increased risk of ovarian</p>
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<p>1 18.</p> <p>2 MS. MILLER: Oh, sorry, I was</p> <p>3 on page 4. I thought you said</p> <p>4 factors.</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. See endometriosis?</p> <p>7 Do you see that?</p> <p>8 A. I do see that.</p> <p>9 Q. See it talks about this is an</p> <p>10 established risk of ovarian cancer? The</p> <p>11 magnitude of the effect is described as</p> <p>12 modest with 1.8 to 2.4.</p> <p>13 MS. MILLER: Objection.</p> <p>14 Mischaracterizes the document.</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. Do you see that?</p> <p>17 A. I see a statement that says,</p> <p>18 magnitude of effect --</p> <p>19 Q. Okay.</p> <p>20 A. -- modest with observed</p> <p>21 relative risks of 1.8 to 2.4.</p> <p>22 Q. Do you see magnitude of effect</p> <p>23 for hormone replacement therapy, modest with</p> <p>24 observed relative risk, 1.20 to 1.8?</p> <p>25 A. I do see the statement</p>	<p>1 cancer, and they defined it as a 1.1.</p> <p>2 Do you see that?</p> <p>3 A. I see, based on fair evidence,</p> <p>4 increases in height and body mass indexes are</p> <p>5 associated with a modest increase in risk of</p> <p>6 ovarian cancer.</p> <p>7 And then where are you seeing</p> <p>8 the 1.1?</p> <p>9 Q. The next paragraph.</p> <p>10 A. I do see that.</p> <p>11 Q. So the National Cancer</p> <p>12 Institute, at least with respect to ovarian</p> <p>13 cancer, has classified modest increases from</p> <p>14 anywhere between 1.1 all the way up to 2.0 as</p> <p>15 modest, correct?</p> <p>16 MS. MILLER: Objection.</p> <p>17 MR. LOCKE: Objection.</p> <p>18 THE WITNESS: Again, I'm not</p> <p>19 sure who put this all together, but if</p> <p>20 I were to give a presentation and</p> <p>21 say -- in a classroom or in a lecture</p> <p>22 or in my research progress and said</p> <p>23 that a risk ratio of 1.1 was modest,</p> <p>24 I'd get laughed out of the room.</p> <p>25 QUESTIONS BY MR. TISI:</p>

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<p>1 Q. So this is a laughable 2 document, huh? 3 MR. LOCKE: Objection. 4 THE WITNESS: I'm not saying 5 I'm laughing at this, but I'm just 6 telling you that if Dr. Gordis came 7 into the room and I tried to explain 8 to him that a relative risk of 1.1 is 9 modest, he'd laugh me out of the room. 10 QUESTIONS BY MR. TISI: 11 Q. Now he's an expert? 12 A. I'm not saying he's an expert. 13 Q. Okay. 14 A. He was my teacher. 15 Q. Okay. 16 A. And I wouldn't do that in front 17 of him. 18 (Merlo Exhibit 32 marked for 19 identification.) 20 QUESTIONS BY MR. TISI: 21 Q. Okay. Let's look at Exhibit 22 Number 32, which is another chapter out of 23 the textbook Modern Epidemiology by 24 Dr. Rothman, which I have marked as Exhibit 25 Number 32. And on page 25 of 30, it talks</p>	<p>1 But because of other factors, 2 maybe factors, considerations that Bradford 3 Hill has, such as consistency or dose 4 response, do lead one to conclude that 5 there's a causal association between exposure 6 and outcome. 7 And if we're talking about 8 environmental tobacco smoke and lung cancer, 9 studies are consistent, and there's a 10 consistent dose response. 11 Q. They all show -- they all 12 show -- they all show statistically 13 significant associations. Every cohort and 14 case-control study shows consistent 15 association in secondhand smoke; is that what 16 you're testifying to? 17 MS. MILLER: Objection. 18 MR. LOCKE: Objection. 19 THE WITNESS: I didn't say 20 that. 21 QUESTIONS BY MR. TISI: 22 Q. Okay. 23 A. I said that there's 24 consistency. And there's consistency in the 25 literature that secondhand smoke in</p>
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<p>1 about the strength criteria. 2 He says -- and I want to ask 3 you whether you agree with it or not -- under 4 the strength of association, second -- two 5 sentences from the bottom of the first 6 paragraph, "Of special importance, Cornfield, 7 et al., acknowledged that having only a weak 8 association does not rule out causal 9 association. Today, some associations, such 10 as those between smoking and cardiovascular 11 disease or between environmental tobacco 12 smoke and lung cancer are accepted by most as 13 causal, even though the associations are 14 considered weak." 15 Do you agree with that? 16 A. So I'm going to -- if you just 17 give me a second to read it over again. 18 Q. Uh-huh. 19 A. Because I'm seeing this for the 20 first time. 21 So again, we're talking about 22 generalizations here, and there are -- there 23 may be instances where a relative risk or an 24 odds ratio is less than 2, and it's 25 considered a weak association.</p>	<p>1 sufficient dose over sufficient time -- so a 2 dose response plus consistency -- can lead 3 one to conclude that there is a causal 4 association between secondhand smoke and, 5 say, lung cancer. 6 Q. So where is the statement that 7 you have to -- in the absence of a high risk 8 ratio or in the presence of a weak risk ratio 9 that you need to have dose response and 10 consistency? 11 A. Because -- 12 Q. Or is that -- is that your 13 postulate? 14 A. No, that is not my postulate. 15 That's -- those things oftentimes go 16 hand in hand. And the reason I say this, if 17 there's a relative risk of 200, it's going to 18 be very difficult to explain that away. 19 Say we used the pulmonary 20 hypertension example. The odds ratio is 23 21 for patients that use that medication for 22 more than three months. So -- and that gets 23 at the dose response and gets at the factors 24 that may -- the other considerations that 25 Bradford Hill brought out, namely, namely,</p>

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<p>1 the dose response.</p> <p>2 So secondhand smoke over a</p> <p>3 sufficient amount of time, given a sufficient</p> <p>4 amount of exposure, even though there may be</p> <p>5 a weak relative risk, that potentially could</p> <p>6 be a causal -- could -- one could conclude</p> <p>7 causality because of the other considerations</p> <p>8 that are present.</p> <p>9 Q. On the next page -- I'm going</p> <p>10 to ask you about secondhand smoke. Before I</p> <p>11 do, let's go to the next page. It says,</p> <p>12 "These examples remind us that a strong</p> <p>13 association is neither necessary nor</p> <p>14 sufficient for causality and that weakness</p> <p>15 isn't even necessary nor sufficient for the</p> <p>16 absence of causality."</p> <p>17 Do you see that?</p> <p>18 A. Is that the second sentence on</p> <p>19 the top?</p> <p>20 Q. Yes. "These examples remind us</p> <p>21 that a strong association is neither</p> <p>22 necessary nor sufficient for causality and</p> <p>23 that weakness is neither necessary nor</p> <p>24 sufficient for absence of causality."</p> <p>25 Do you agree with that?</p>	<p>1 objection that this is an excerpt that</p> <p>2 was cut off at the end, and it's not a</p> <p>3 complete chapter or a complete</p> <p>4 anything.</p> <p>5 MR. TISI: Okay. Well, it's a</p> <p>6 complete paragraph that talks about</p> <p>7 the strength of association, so</p> <p>8 let's...</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: I'm sorry, I just</p> <p>11 need a little bit of time to find it.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. That's fine.</p> <p>14 A. Okay. So I have three pages</p> <p>15 photocopied here.</p> <p>16 Q. Correct.</p> <p>17 So if you go to the last page,</p> <p>18 it has a paragraph with a bullet point that</p> <p>19 says, "Strength of Association."</p> <p>20 Do you see that?</p> <p>21 And if you read it and tell me</p> <p>22 where Dr. Oleckno talks about strong,</p> <p>23 moderate and weak associations.</p> <p>24 MS. MILLER: Objection.</p> <p>25 MR. LOCKE: Objection.</p>
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<p>1 A. So I think that this is one of</p> <p>2 the -- one of the things that Bradford Hill</p> <p>3 in his article said, that these are</p> <p>4 considerations, and that if there is a risk</p> <p>5 ratio, whether it's a relative risk or a odds</p> <p>6 ratio of 200, it's difficult to explain that</p> <p>7 away.</p> <p>8 Could it be explained away?</p> <p>9 Sure, if we didn't measure some factor that</p> <p>10 is associated with the exposure and the</p> <p>11 outcome and is not in between the causal</p> <p>12 pathway. But it -- it's a reason to use</p> <p>13 these as considerations.</p> <p>14 And further, if we're talking</p> <p>15 about a weak association, say a weak relative</p> <p>16 risk or odds ratio, that less than 2, if</p> <p>17 there are other considerations that add to</p> <p>18 it, say dose response or consistency among</p> <p>19 studies, then that supports causality.</p> <p>20 Q. Let me go to the Oleckno</p> <p>21 article -- the Oleckno textbook again, and</p> <p>22 let me ask you this. He also -- it's the</p> <p>23 same one we talked about before. So we can</p> <p>24 go to Exhibit Number 22.</p> <p>25 MS. MILLER: I have the same</p>	<p>1 THE WITNESS: I think the</p> <p>2 Oleckno textbook says in general, the</p> <p>3 stronger an association between a</p> <p>4 given exposure and outcome, the more</p> <p>5 likely association is causal.</p> <p>6 It's also referencing a table,</p> <p>7 6.3, which is not here, so I'm not</p> <p>8 sure how I can even answer that.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Yeah, but you said -- but,</p> <p>11 Doctor, you said here -- you said here at the</p> <p>12 end "by definition." You use the phrase "by</p> <p>13 definition," "a 1.2 to 1.6 by definition is</p> <p>14 weak."</p> <p>15 And I don't see that</p> <p>16 definition, so you need to tell me where that</p> <p>17 definition is.</p> <p>18 A. It's an accepted definition in</p> <p>19 epidemiology.</p> <p>20 MS. MILLER: Objection.</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. By whom?</p> <p>23 A. Epidemiologists.</p> <p>24 Q. Where?</p> <p>25 I've gone through every</p>



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<p>1 textbook and I've never seen a definition, 2 and you don't provide it. So I want to know 3 where you find it -- 4 MR. LOCKE: Objection. 5 MS. MILLER: Objection. 6 QUESTIONS BY MR. TISI: 7 Q. -- other than the Australian 8 thing that we talked about before. Where? 9 MS. MILLER: Objection. 10 MR. LOCKE: Objection. 11 THE WITNESS: It's in my 12 reference. We can pull that and look 13 at it, if you'd like. 14 QUESTIONS BY MR. TISI: 15 Q. Okay. I'm going to find it in 16 your references? 17 A. It's that reference. 18 Q. Okay. That Australian white 19 paper? 20 MS. MILLER: Objection. 21 THE WITNESS: Let me look 22 through. I'll look through my report 23 again. 24 QUESTIONS BY MR. TISI: 25 Q. Actually, Doctor, I think</p>	<p>1 MR. LOCKE: Objection. 2 MS. MILLER: Objection. 3 QUESTIONS BY MR. TISI: 4 Q. You're cherry-picking. 5 I'm going to show you what 6 Dr. Siemiatycki says. Actually, let me just 7 choose actually -- I'm going to choose 8 Dr. Siemiatycki. Here's his report. I'm 9 going to attach it as Exhibit Number 33, his 10 discussion of that issue. 11 (Merlo Exhibit 33 marked for 12 identification.) 13 QUESTIONS BY MR. TISI: 14 Q. He's one of the people you 15 criticize, right? 16 A. I critiqued plaintiffs' 17 reports. 18 Q. Right. 19 And you say, "Dr. Siemiatycki 20 states," and you have a quote, which indeed I 21 will tell you appears in the report, but it's 22 not the whole thing of what he says. Does 23 it -- would you agree? 24 MS. MILLER: Objection. 25 THE WITNESS: Can you ask that</p>
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<p>1 that's where it is. I'm not going to ask you 2 to move on. 3 But you criticize plaintiffs' 4 experts because they say -- they call this 5 strong, this 1.2 to 1.6 as strong. 6 Do you see that? Page 43 of 7 your report? 8 A. I do see that. Plaintiffs' 9 epidemiologists find a strong association. 10 Q. Did you actually read their 11 reports? 12 A. I did. 13 MR. LOCKE: Objection. 14 QUESTIONS BY MR. TISI: 15 Q. Did you read their depositions? 16 A. I did. 17 Q. Did you read -- did you read 18 where they explained what they were talking 19 about in terms of strength of association? 20 MS. MILLER: Objection. 21 THE WITNESS: So you would have 22 to -- 23 QUESTIONS BY MR. TISI: 24 Q. I mean, you're cherry-picking 25 what they said, aren't you?</p>	<p>1 again? I'm not sure what you're 2 asking me. 3 QUESTIONS BY MR. TISI: 4 Q. Yes. I'm going to read his 5 section that talks about strength of 6 association. 7 MS. MILLER: I'm going to 8 object to this -- 9 MR. TISI: Of course you're 10 going to object because it's -- 11 MS. MILLER: -- specific 12 because it's page 19 and then it's 13 page 62, 63, 87, 88, 82. 14 MR. TISI: Yes. These are the 15 two -- this is every place in his 16 report where he talks about strength 17 of association. Absolutely. 18 MS. MILLER: Well, I don't have 19 a need to know that. 20 MR. TISI: Including -- 21 actually, it has -- it has the -- it 22 has the very quote that this doctor 23 put in his report, and I'll put it 24 there. It's page 63. "Such a high 25 and significant meta-analysis research</p>

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<p>1 risk ratio could not have occurred by 2 chance." 3 QUESTIONS BY MR. TISI: 4 Q. Do you see that? 5 MR. LOCKE: Objection. 6 QUESTIONS BY MR. TISI: 7 Q. It's on page 63, and that's the 8 quote you had. 9 MS. MILLER: You objected to 10 cherry-picking. These are seven 11 cherry-picked pages from an expert 12 report. 13 MR. TISI: They're not 14 cherry-picked pages. Every part that 15 talks about -- 16 MS. MILLER: I don't know what 17 cherry-picked means to you, but -- 18 MR. TISI: Well, Counsel, then 19 keep your objections to yourself. 20 MR. LOCKE: Objection. 21 MR. TISI: "Objection, form," 22 is fine. 23 QUESTIONS BY MR. TISI: 24 Q. Doctor, this is the paragraph 25 that you quote in your report, correct? It's</p>	<p>1 That means the best estimate from an ep -- 2 from the epidemiologic literature is that 3 women who regularly used talcum powder 4 products in the genital area had a 28 percent 5 higher risk of ovarian cancer than a woman 6 who did not use such powder. As I illustrate 7 in Table 11, which I attach" -- because it 8 refers to there, if you take a look on 9 page -- at the -- on page 87, it has a 10 Table 11. He lists numerous kinds of -- 11 urban air pollution, trichloroethylene, 12 diesel engine emissions, benzene, domestic 13 radon gas, secondhand cigarette smoke, 14 intermittent, intense sun exposure, et 15 cetera. He lists a lot of them, all within a 16 relative risk of 1.09, with the highest being 17 1.64. 18 Do you see that table? 19 A. I do. 20 Q. "As I illustrate in Table 11 21 with a few examples, this relative risk is in 22 line with well-recognized risk factors for 23 cancer and other diseases. For example, it 24 is well-accepted now that people living in an 25 urban neighborhood in which there is -- in</p>
Page 327	Page 329
<p>1 the last sentence of a full paragraph. 2 A. I'd have to look at his full 3 report to know if that's the one I'm quoting. 4 Said that again somewhere. 5 Q. Okay. Doctor, it says, "Such a 6 high" -- you look at your report on page 43. 7 It says, "Such a high and significant," in 8 parentheses, "relative risk could not have 9 occurred by chance." And that's the sentence 10 on page 63. 11 A. So we're looking at page 63 12 of -- 13 Q. Correct. 14 A. -- Dr. Siemiatycki's report. 15 Q. Right. 16 And that's at the end of a 17 paragraph, right? 18 A. That's at the end of a 19 paragraph. 20 Q. Okay. So let's look at what he 21 says before that. 22 "Strength of association. This 23 can embody both the magnitude of the relative 24 risk and its statistical significance. The 25 meta-analysis risk ratio estimate is 1.28.</p>	<p>1 which the air is highly polluted with 2 particulate matter have a 5 to 10 percent 3 excess risk of lung cancer compared to people 4 living in a less polluted urban neighborhood. 5 Also is well-accepted that workers exposed to 6 a solvent called trichloroethylene had about 7 a 40 percent higher chance of kidney cancer 8 compared to workers not exposed to 9 trichloroethylene. Thus, the 28 percent 10 increase in ovarian cancer for women who used 11 talcum powder products is in line with many 12 risk factors. This increased risk is 13 manifested by a meta research -- meta risk 14 ratio that is statistically significant." 15 And then it has the sentence you quoted. 16 He's very clear about the range 17 of relative risks and compares it to a number 18 of other well-accepted carcinogens, does he 19 not? 20 MS. MILLER: Objection. 21 MR. LOCKE: Objection. 22 THE WITNESS: I see that there 23 is a comparison to other agents and 24 potential risk for disease in those 25 agents.</p>

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<p style="text-align: right;">Page 330</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. And you --</p> <p>3 A. However, this says nothing</p> <p>4 about the strength of association. It just</p> <p>5 says that there's an association between</p> <p>6 these agents and this disease with this</p> <p>7 relative risk.</p> <p>8 These are all under 2. That</p> <p>9 doesn't -- that says nothing about the</p> <p>10 strength. It's a weak association of all of</p> <p>11 them.</p> <p>12 Q. Okay. Then he goes on and he's</p> <p>13 asked about that in his deposition, and I'm</p> <p>14 going to attach that. And I'm not going to</p> <p>15 spend a lot of time on it, but for the</p> <p>16 record, that will be on the record, Exhibit</p> <p>17 Number 34.</p> <p>18 (Merlo Exhibit 34 marked for</p> <p>19 identification.)</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. And did you cite anything from</p> <p>22 his deposition?</p> <p>23 MS. MILLER: Objection.</p> <p>24 THE WITNESS: I'd have to look</p> <p>25 through my report.</p>	<p style="text-align: right;">Page 332</p> <p>1 MS. MILLER: Again, I'm going</p> <p>2 to have to have the same objection. I</p> <p>3 don't know why you didn't just provide</p> <p>4 the entire expert report.</p> <p>5 This is pages 11, 12, 13, 14,</p> <p>6 15, 16. We don't have pages 1 to 10.</p> <p>7 We don't have --</p> <p>8 MR. TISI: Counsel, I got your</p> <p>9 objection. I got your --</p> <p>10 MS. MILLER: -- pages after 16,</p> <p>11 and page 16 ends in the middle of a</p> <p>12 sentence.</p> <p>13 MR. TISI: I got your -- I got</p> <p>14 your objection, Counsel.</p> <p>15 MR. LOCKE: Same objection.</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. Doctor, can you turn to page 15</p> <p>18 of Dr. Moorman's report, which I have put</p> <p>19 here, which I will represent to you is a</p> <p>20 whole section on strength of association.</p> <p>21 She has a paragraph, "The</p> <p>22 overall association seen in talc/ovarian</p> <p>23 cancer meta-analyses, as well as many other</p> <p>24 individual studies, are statistically</p> <p>25 significant, indicating an increased risk of</p>
<p style="text-align: right;">Page 331</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. Let me show you another</p> <p>3 example: Dr. Moorman. Dr. Moorman, who you</p> <p>4 also criticize as saying, "Taken as a whole,</p> <p>5 the overwhelming statistical strength of</p> <p>6 these studies" -- sorry, "by the strength of</p> <p>7 the studies, whose results are replicated</p> <p>8 over decades and over a wide variety of</p> <p>9 populations and investigators, further</p> <p>10 supported by consistent meta-analysis, weigh</p> <p>11 heavily in favor of a causal inference."</p> <p>12 That was what you said that</p> <p>13 Dr. Moorman said, correct?</p> <p>14 A. You'd have to refer to me where</p> <p>15 I said that.</p> <p>16 Q. On page 43 and 44 of your</p> <p>17 report.</p> <p>18 A. And I apologize. I don't have</p> <p>19 these -- this memorized. So, you know,</p> <p>20 you're reading stuff --</p> <p>21 Q. Well, I do, and I didn't write</p> <p>22 it. Here you go.</p> <p>23 MS. MILLER: Objection.</p> <p>24 (Merlo Exhibit 35 marked for</p> <p>25 identification.)</p>	<p style="text-align: right;">Page 333</p> <p>1 approximately 25 to 30 percent. While not as</p> <p>2 high as other relationship, like smoking and</p> <p>3 lung cancer, these relative risks are in line</p> <p>4 with other generally accepted causal</p> <p>5 relationships. Example, secondhand smoke and</p> <p>6 lung cancer: I consider the strength of</p> <p>7 association as seen in the ovarian cancer</p> <p>8 epidemiologic studies to be an important</p> <p>9 factor in favor of a causal relationship</p> <p>10 between talc and ovarian cancer, particularly</p> <p>11 when considered along with the consistency</p> <p>12 and association seen across these studies."</p> <p>13 Dr. Moorman is not -- has</p> <p>14 characterized what the studies show. The</p> <p>15 numbers are the numbers, correct?</p> <p>16 MS. MILLER: Objection.</p> <p>17 MR. LOCKE: Objection.</p> <p>18 THE WITNESS: You'd have to</p> <p>19 show me what you're referring to. The</p> <p>20 numbers are the numbers.</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. All right. Well, let's do</p> <p>23 that. Dr. Moorman --</p> <p>24 MS. MILLER: This is only part</p> <p>25 of her report, and it's not the part</p>

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<p>1 of her report that he cites. Is that 2 correct? 3 (Merlo Exhibit 36 marked for 4 identification.) 5 QUESTIONS BY MR. TISI: 6 Q. Here's your -- here's Exhibit 7 Number 36, please. 8 She's asked the questions on 9 page 249 of her report -- of her deposition. 10 "I think you're conflating or 11 misunderstanding my question." This is the 12 Johnson &amp; Johnson lawyer asking the question. 13 "I think you're conflating or 14 you're misunderstanding my question because 15 you're answering the question" -- 16 A. I'm sorry, where are we? 17 Q. Page 249, starting on line 3. 18 Okay? "And I think you're 19 conflating or you're misunderstanding my 20 question because you're answering the 21 question about whether the association is 22 real or not real, and my question for you is 23 whether the association is weak, modest or 24 strong. How would you characterize it?" to 25 Dr. Moorman.</p>	<p>1 saying that I think it's more accurate 2 just to describe it as it is, a 25 to 3 30 percent increase of risk of ovarian 4 cancer, but I don't know what she's 5 referring to there -- 6 QUESTIONS BY MR. TISI: 7 Q. Okay. 8 A. -- whether that's one study, 9 all studies, a meta-analysis, anything. 10 Q. Okay. 11 A. One could also say that a 12 relative risk of 1.25 or 1.30 is a weak 13 association. 14 Q. Okay. But you are 15 characterizing what they testified to, and 16 you were cherry-picking statements from their 17 report, were you not? 18 MS. MILLER: Objection. 19 MR. LOCKE: Objection. 20 THE WITNESS: I don't know what 21 you mean by "cherry-picking." 22 QUESTIONS BY MR. TISI: 23 Q. Meaning taking -- 24 A. I read their depositions -- 25 sorry, I read their reports and I critiqued</p>
Page 335	Page 337
<p>1 Her answer: "Answer, as I 2 would -- as I have said, there is no absolute 3 terminology that would say what is a weak 4 association, what is modest and what is 5 strong. So I think it is more accurate just 6 to describe it as it is, a 25 to 30 percent 7 increased risk of ovarian cancer." 8 Do you see that? 9 A. I see that. 10 Q. Okay. She didn't characterize 11 it as strong, did she? 12 MS. MILLER: Objection. 13 MR. LOCKE: Objection. 14 QUESTIONS BY MR. TISI: 15 Q. She characterized it by the 16 number, correct? 17 MS. MILLER: Objection. 18 MR. LOCKE: Objection. 19 MS. MILLER: Are you asking 20 ever or here or -- 21 MR. TISI: I'm asking -- I'm 22 asking when she was asked the question 23 at deposition. 24 MR. LOCKE: Objection. 25 THE WITNESS: Dr. Moorman is</p>	<p>1 their reports. And by saying that a relative 2 risk of 1.2 is a strong association is so far 3 out of line of the epidemiologic community 4 that that is my critique. 5 MR. TISI: Okay. We're about 6 ready to go into a new area, so if you 7 want to take a break, this is a good 8 time unless you want me to just plow 9 forward. 10 MS. MILLER: How long is the 11 next area? 12 MR. TISI: I have no idea. It 13 depends on whether he says "it 14 depends" all the time. 15 MR. LOCKE: Objection. 16 THE WITNESS: I can take a 17 break. 18 MR. TISI: Perfect. 19 THE WITNESS: Get some coffee. 20 MR. TISI: Perfect. 21 VIDEOGRAPHER: The time is 22 3:01 p.m. We're going off the record. 23 (Off the record at 3:01 p.m.) 24 VIDEOGRAPHER: The time is 25 3:16 p.m., and we're back on the</p>

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<p style="text-align: right;">Page 338</p> <p>1 record.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Doctor, could you go to page 31</p> <p>4 of your report? I'm going to talk about</p> <p>5 consistency and statistical significance.</p> <p>6 A. Sure.</p> <p>7 Q. We've spent a lot of time</p> <p>8 talking about consistency and your opinion</p> <p>9 that there is no consistency, so I think</p> <p>10 we'll be able to go through this pretty</p> <p>11 quickly.</p> <p>12 But if you go to page 31, you</p> <p>13 criticize plaintiffs' experts -- well, you</p> <p>14 say, "Lack of consistency between studies.</p> <p>15 One of the most striking aspects of their</p> <p>16 studies is their inconsistency."</p> <p>17 Do you see that?</p> <p>18 A. No.</p> <p>19 Where am I saying that?</p> <p>20 Q. First sentence of your</p> <p>21 Section A on page 31.</p> <p>22 A. Okay.</p> <p>23 Q. Okay. And you note, and I'm</p> <p>24 summarizing here, that there are seven</p> <p>25 hospital-based studies, four cohort studies</p>	<p style="text-align: right;">Page 340</p> <p>1 are the risk ratios, correct?</p> <p>2 A. Yes, the first column's the</p> <p>3 study authors and the dates. The second</p> <p>4 column is either the odds ratio, relative</p> <p>5 risk or hazard ratio.</p> <p>6 Q. Can we call them risk ratios</p> <p>7 generally?</p> <p>8 Can we call them -- is there a</p> <p>9 general -- I thought we could call them risk</p> <p>10 ratios, but --</p> <p>11 A. Sure. It's just that in an --</p> <p>12 an odds ratio is something that's determined</p> <p>13 in a case-control study and a relative risk,</p> <p>14 which in a hazard ratio deal with time, and</p> <p>15 those are involved in cohort studies.</p> <p>16 Q. I understand. I understand.</p> <p>17 But the second column are the</p> <p>18 risk ratios generally?</p> <p>19 A. Estimates of risk, yes.</p> <p>20 Q. Estimates of risk.</p> <p>21 And the third column are the</p> <p>22 confidence interval.</p> <p>23 And tell me what a confidence</p> <p>24 interval is.</p> <p>25 A. A confidence interval is when</p>
<p style="text-align: right;">Page 339</p> <p>1 and some population studies that have</p> <p>2 statistically insignificant results.</p> <p>3 And we talked about that</p> <p>4 before; do you recall?</p> <p>5 A. We talked about cohort studies.</p> <p>6 We talked about hospital-based studies. We</p> <p>7 talked about population-based studies. We</p> <p>8 talked about statistical significance in</p> <p>9 population-based studies as well as</p> <p>10 statistical insignificance in</p> <p>11 population-based studies as well as</p> <p>12 statistical insignificance in hospital-based</p> <p>13 and statistical insignificance within cohort</p> <p>14 studies.</p> <p>15 Q. Right.</p> <p>16 And on page 34 of your report,</p> <p>17 you have a chart that you put in summarizing</p> <p>18 the studies, correct?</p> <p>19 A. Page 34 is a chart that</p> <p>20 summarizes case-control studies as well as</p> <p>21 cohort studies, and the case controls are</p> <p>22 broken down into hospital-based and</p> <p>23 population-based.</p> <p>24 Q. And the first column is</p> <p>25 actually the study name. The second column</p>	<p style="text-align: right;">Page 341</p> <p>1 you do an analysis and you get a -- some</p> <p>2 estimate of risk, some point estimate, which</p> <p>3 would be that second column. Then you're</p> <p>4 given -- then you obtain what's called a</p> <p>5 95 percent confidence interval, which is sort</p> <p>6 of the range within statistical significance</p> <p>7 where that point estimate might fall.</p> <p>8 Q. Right.</p> <p>9 A. And in general, when the</p> <p>10 95 percent confidence interval overlies 1,</p> <p>11 that signifies a nonstatistically significant</p> <p>12 point -- estimate of risk.</p> <p>13 Q. But the confidence interval</p> <p>14 encompasses the range of likely -- where the</p> <p>15 likely results are likely to be to a</p> <p>16 95 percent certainty?</p> <p>17 A. The -- I don't know that I</p> <p>18 would say certainty. I think it's the --</p> <p>19 it's the range of the -- it's the range of</p> <p>20 the point estimate above which or below which</p> <p>21 there would be a 2.5 percent chance of that</p> <p>22 point estimate falling.</p> <p>23 Q. Okay.</p> <p>24 A. And the confidence interval can</p> <p>25 either be wide or narrow. The wider it is,</p>

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<p style="text-align: right;">Page 342</p> <p>1 that usually relates to heterogeneity within</p> <p>2 the study, a small study population, problems</p> <p>3 in collecting appropriate information.</p> <p>4 If the confidence interval is</p> <p>5 narrow, usually that reflects a larger study</p> <p>6 population.</p> <p>7 Q. And the last column is your</p> <p>8 assessment of the strength of the</p> <p>9 association, if there is one, right?</p> <p>10 You say, "Is it a statistically</p> <p>11 significant association?"</p> <p>12 And that's your interpretations</p> <p>13 here, correct?</p> <p>14 A. It says, "If there's a</p> <p>15 statistically significant association."</p> <p>16 That's what's reported in the journal.</p> <p>17 Q. Okay. And then the "no" in the</p> <p>18 last column stands for not statistically</p> <p>19 significant?</p> <p>20 A. The "no" stands for not</p> <p>21 statistically significant, that's correct.</p> <p>22 Q. And the "weak" stands for</p> <p>23 statistically significant and with your</p> <p>24 characterization of the strength of the</p> <p>25 association?</p>	<p style="text-align: right;">Page 344</p> <p>1 separate exhibit.</p> <p>2 (Merlo Exhibit 37 marked for</p> <p>3 identification.)</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. And I'm going to do it Exhibit</p> <p>6 Number 37.</p> <p>7 A. Thank you.</p> <p>8 Q. I'm going to come back to it,</p> <p>9 and I don't want to keep flipping back and</p> <p>10 forth to the pages.</p> <p>11 A. Okay.</p> <p>12 Q. And this is your -- this chart</p> <p>13 summarizes the -- the last column here</p> <p>14 summarizes your view of the inconsistency of</p> <p>15 these studies. The now are inconsistency</p> <p>16 with the weak's?</p> <p>17 MS. MILLER: Objection.</p> <p>18 THE WITNESS: So what -- not</p> <p>19 only that, I mean, what this does</p> <p>20 summarize, inconsistency within</p> <p>21 population-based case-control studies</p> <p>22 where some studies show a weak</p> <p>23 statistically significant association</p> <p>24 while some studies do not show any</p> <p>25 statistically significant association.</p>
<p style="text-align: right;">Page 343</p> <p>1 A. The "weak" stands for a weak</p> <p>2 statistically significant association.</p> <p>3 Q. But that's your</p> <p>4 characterization; that's not the authors'?</p> <p>5 A. That is what is -- they're all</p> <p>6 below 2, statistically significant --</p> <p>7 Q. Okay.</p> <p>8 A. Which -- suggests a weak</p> <p>9 association, yes.</p> <p>10 Q. Okay. And just to be clear,</p> <p>11 you can't point to me any textbook in</p> <p>12 epidemiology where it is universally accepted</p> <p>13 that a risk ratio of 1.17, which is one of</p> <p>14 the things -- to 1.92 is weak. That's just</p> <p>15 your view of what the scientific community</p> <p>16 says?</p> <p>17 MS. MILLER: Objection.</p> <p>18 MR. LOCKE: Objection.</p> <p>19 THE WITNESS: It's not my view</p> <p>20 of what the scientific community says.</p> <p>21 It's what the scientific community</p> <p>22 says.</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. Okay. And you -- okay. I'd</p> <p>25 like to make this chart a separate chart -- a</p>	<p style="text-align: right;">Page 345</p> <p>1 But there's also differences</p> <p>2 in -- within study -- the same study</p> <p>3 design. Say, within case controls,</p> <p>4 hospital-based case controls, there</p> <p>5 are seven of them, and none of them</p> <p>6 have a statistically significant</p> <p>7 association, and therefore case con --</p> <p>8 sorry, four cohort studies which do</p> <p>9 not show any statistically</p> <p>10 significant.</p> <p>11 So it's not just summarizing</p> <p>12 the differences in that column, it's</p> <p>13 summarizing the differences between</p> <p>14 study types and the differences within</p> <p>15 a similar study.</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. Understood. And I hear you.</p> <p>18 And what I'm trying to say is,</p> <p>19 it's your view that a weak statistically</p> <p>20 significant result is inconsistent with a</p> <p>21 non -- and I think you agreed to this before,</p> <p>22 but I want to make sure.</p> <p>23 MS. MILLER: No.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. That a weak statistically</p>

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<p style="text-align: right;">Page 346</p> <p>1 significant result is inconsistent with a --</p> <p>2 for example, let's go back down here. Let's</p> <p>3 take -- see the Rosenblatt study, which was</p> <p>4 one that was done at your institution. That</p> <p>5 has -- was nonstatistically significant, in</p> <p>6 your view, and that is inconsistent with</p> <p>7 Cramer, which is -- shows a weak -- a weak</p> <p>8 statistically significant results.</p> <p>9 MS. MILLER: Objection. That</p> <p>10 mischaracterizes either his report or</p> <p>11 his testimony, whichever it is that</p> <p>12 you're characterizing.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. Doctor, is it your view that,</p> <p>15 using the example I just took, Cramer is</p> <p>16 inconsistent with Rosenblatt?</p> <p>17 A. Which Cramer?</p> <p>18 Q. Cramer 1982 and Rosenblatt</p> <p>19 1992.</p> <p>20 A. So Cramer 1982 shows a point</p> <p>21 estimate of 1.92, and the 95 percent</p> <p>22 confidence interval is 1.27 to 2.89.</p> <p>23 Rosenblatt, 1.27 --</p> <p>24 Q. No, Rosenblatt -- Rosenblatt</p> <p>25 1992, which is a hospital-based study.</p>	<p style="text-align: right;">Page 348</p> <p>1 was such a loaded question.</p> <p>2 MR. TISI: Oh, it is. It's a</p> <p>3 loaded -- it's a loaded headnote.</p> <p>4 THE WITNESS: So I'm not</p> <p>5 accusing anybody of anything.</p> <p>6 MS. MILLER: Objection.</p> <p>7 THE WITNESS: I'm just</p> <p>8 reporting what the medical evidence</p> <p>9 shows. And the medical evidence shows</p> <p>10 that there is inconsistency among</p> <p>11 similar study designs, inconsistency</p> <p>12 between hospital-based and</p> <p>13 population-based case controls,</p> <p>14 inconsistency among population</p> <p>15 case-controls, and inconsistency</p> <p>16 between cohort studies and case</p> <p>17 controls, all leading to</p> <p>18 inconsistency.</p> <p>19 I'm not accusing anyone of</p> <p>20 anything. I'm just reporting what's</p> <p>21 in the medical literature.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Okay. So but you didn't just</p> <p>24 say they're inconsistent result. You say</p> <p>25 plaintiffs' experts fabricate consistency</p>
<p style="text-align: right;">Page 347</p> <p>1 A. Rosenblatt '92. Okay.</p> <p>2 Q. A hospital-based study.</p> <p>3 A. So that's a 1.7, with the</p> <p>4 95 percent confidence interval .7 to 3.9.</p> <p>5 Now, Cramer 1982 is</p> <p>6 statistically significant. Rosenblatt '92 --</p> <p>7 Cramer '82, statistically significant;</p> <p>8 Rosenblatt '92, not statistically</p> <p>9 significance.</p> <p>10 Q. And are those inconsistent?</p> <p>11 MS. MILLER: Objection.</p> <p>12 THE WITNESS: One is</p> <p>13 statistically significant, and one is</p> <p>14 not statistically significant. They</p> <p>15 are inconsistent with each other.</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. Okay. So and on page 44 and 45</p> <p>18 of your report, you criticize plaintiffs'</p> <p>19 experts. You say, "I would agree" -- you</p> <p>20 see, this is the part where you accuse them</p> <p>21 of fabrication. Page 44. "Plaintiffs'</p> <p>22 experts fabricate consistency by ignoring</p> <p>23 inconsistent studies," that heading.</p> <p>24 Do you see that?</p> <p>25 MS. MILLER: Objection. That</p>	<p style="text-align: right;">Page 349</p> <p>1 when there is none. Right?</p> <p>2 So that's -- I mean, maybe I'm</p> <p>3 splitting hairs, but that's a little bit more</p> <p>4 inflammatory than just simply saying, I find</p> <p>5 the studies inconsistent. Right?</p> <p>6 MS. MILLER: Objection.</p> <p>7 MR. LOCKE: Objection.</p> <p>8 THE WITNESS: I don't know. I</p> <p>9 don't know what your definition of</p> <p>10 inflammatory is.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Okay. I think if somebody</p> <p>13 accused you of fabrication, you might be</p> <p>14 thinking that that might be inflammatory, but</p> <p>15 we'll see.</p> <p>16 MR. LOCKE: Objection.</p> <p>17 QUESTIONS BY MR. TISI:</p> <p>18 Q. Let's move on.</p> <p>19 You say plaintiffs' experts</p> <p>20 uniformly assert -- I'm sorry, uniformly</p> <p>21 assert consistent criterion has been</p> <p>22 satisfied, and then you go on to say, "I</p> <p>23 would agree with plaintiffs' experts that</p> <p>24 there's some consistencies among the study,</p> <p>25 but those consistencies are among the</p>



<p style="text-align: right;">Page 350</p> <p>1 hospital-based case-control studies and among 2 the large cohort studies showing no 3 statistically significant inconsistencies" -- 4 I'm sorry, "showing no association between 5 talc exposure and ovarian cancer. By 6 contrast, the inconsistencies between 7 hospital-based and population-based 8 case-control and within population-based 9 case-control studies." 10 Did I read that right? 11 Actually, let me -- I didn't 12 read it right. Let me read it again. 13 "I would agree with plaintiffs' 14 experts that there are some consistencies 15 between studies, but those consistencies are 16 among hospital-based case-control studies and 17 among large cohort studies showing no 18 statistically significant association between 19 talc exposure and ovarian cancer. By 20 contrast, there are inconsistencies between 21 hospital-based and population-based 22 case-control studies and within 23 population-based case-control studies." 24 Did I read that right? 25 A. Yes, sir.</p>	<p style="text-align: right;">Page 352</p> <p>1 here on -- in retyping this. 2 I did not highlight 3 statistically significant. So if you would 4 just do me a favor and take this pen and 5 circle "statistically significant" in the 6 middle of that paragraph, I'd appreciate 7 that. 8 MS. MILLER: Objection. 9 QUESTIONS BY MR. TISI: 10 Q. Go ahead, if you don't mind. 11 A. What do you want me to do? 12 Q. Just take statistically in -- 13 because in your document, you actually 14 highlight and italicize "statistically 15 significant" in your -- correct? 16 MS. MILLER: Huh? 17 QUESTIONS BY MR. TISI: 18 Q. In your -- on page 45, top 19 paragraph. 20 A. But that's not -- that's not 21 from page 45. This is page 44 from that 22 paragraph. 23 Q. Let me see. Maybe I gave you 24 the wrong one. 25 MS. MILLER: This is the</p>
<p style="text-align: right;">Page 351</p> <p>1 Q. Okay. And then you go on to 2 say -- and this is the statement that we 3 talked about before, the kind of the general 4 rule that you set out. It says, "It is 5 important to remember, contrary to the 6 suggestion of several of plaintiffs' experts 7 on page 45, that for this criteria to weigh 8 in favor of finding a causal relationship, 9 there must be consistency and statistically 10 significant associations. Consistency is -- 11 in relative risks that are not statistically 12 significant is not meaningful because that 13 sort of consistency does not provide any 14 degree of confidence that the claim of 15 association made by the study is more than 16 random chance." 17 Did I read that right? 18 A. That's correct. 19 (Merlo Exhibit 38 marked for 20 identification.) 21 QUESTIONS BY MR. TISI: 22 Q. Okay. Now, I'm going to have 23 that statement marked here as Exhibit 24 Number 38. But I'm going to do this, Doctor, 25 because I have to say that I made a mistake</p>	<p style="text-align: right;">Page 353</p> <p>1 paragraph -- 2 MR. TISI: I apologize. I'm 3 sorry, you're correct. It's 4 Exhibit 39. 5 (Merlo Exhibit 39 marked for 6 identification.) 7 MS. MILLER: So are we done 8 with this one? 9 MR. TISI: I'm just mark it. 10 It's the early part. We'll leave it 11 there. 12 QUESTIONS BY MR. TISI: 13 Q. This is 39. I'm sorry, Doctor. 14 A. That's okay. 15 Q. This is the paragraph on the 16 top of page 45. And I did not emphasize what 17 you emphasized, and I apologize for that. 18 You emphasized statistically 19 significant, and I didn't when I retyped 20 this. So if you would do me a favor and just 21 circle the words "statistically significant," 22 I'd appreciate it. 23 MS. MILLER: I'm going to 24 object to that. I think you should 25 circle it if you want it circled.</p>

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<p style="text-align: right;">Page 354</p> <p>1 THE WITNESS: It's mentioned 2 twice, so -- 3 QUESTIONS BY MR. TISI: 4 Q. Well, the one that you 5 highlighted in your report. 6 A. Looks like -- consistency and 7 statistically significant. This and this. 8 Q. And this is your rule that you 9 set out. It says, "Important to remember," 10 and this is a -- we talked about this earlier 11 in your deposition. Although there is no 12 citation for this, you agree that this is 13 your -- you believe that this is a generally 14 accepted principle in epidemiology? 15 A. It's a generally accepted 16 principle in epidemiology. 17 Q. Okay. Doctor, have you seen 18 references to the fact that statistical 19 significance is not the test of consistency? 20 A. You'd have to show me a 21 reference. 22 Q. Okay, let's do that. Could you 23 go -- can you pull out Exhibit 23, which is 24 the "From Association to Causation" chapter 25 that Johns Hopkins uses in courses there?</p>	<p style="text-align: right;">Page 356</p> <p>1 A. I do see that. 2 Q. Is there any mention of 3 statistical significance in this? 4 MS. MILLER: Objection. 5 THE WITNESS: There is not. 6 QUESTIONS BY MR. TISI: 7 Q. Okay. 8 A. But there's not a reference 9 saying that -- that if it's not there, the 10 opposite. 11 Q. Okay. Does it also talk about 12 there needs to be consistency among study 13 designs? 14 MS. MILLER: Objection. 15 QUESTIONS BY MR. TISI: 16 Q. This talks about among studies 17 but not study design, does it? 18 MS. MILLER: Objection. 19 THE WITNESS: It says, "If an 20 association observed, we would expect 21 it to be seen consistently within 22 subgroups of the population and in 23 different populations," which may 24 involve different studies and 25 different study designs.</p>
<p style="text-align: right;">Page 355</p> <p>1 It's the Gordis text. 2 Do you see that? 3 Do you have it in front of you? 4 A. I have Chapter 14, yes, 5 Exhibit 23. 6 Q. Can you go to page 251. On 7 page -- it talks about Replications of 8 Findings, which is the consistency issue, 9 right? 10 MS. MILLER: Objection. 11 THE WITNESS: I see where it 12 says "Replication of Findings." 13 QUESTIONS BY MR. TISI: 14 Q. And it says, "If the 15 relationship is causal, we would expect to 16 find consistency in different studies and in 17 different populations. Replication of 18 findings is particularly important in 19 epidemiology. If an association as observed, 20 we can also -- we would also expect it to be 21 seen consistently within subgroups of the 22 population and in different populations and 23 unless there is a clear reason to expect 24 different results." 25 Do you see that?</p>	<p style="text-align: right;">Page 357</p> <p>1 QUESTIONS BY MR. TISI: 2 Q. But it doesn't say study 3 designs, does it? 4 MS. MILLER: Objection. 5 THE WITNESS: I don't think it 6 has to. That's inherent in the 7 statement. 8 QUESTIONS BY MR. TISI: 9 Q. Okay. Now, I previously asked 10 you whether you had done any independent 11 research on studies of talc and ovarian 12 cancer, and you said you had not. 13 Do you recall that? 14 MS. MILLER: Objection. 15 QUESTIONS BY MR. TISI: 16 Q. That was very early in the day. 17 MS. MILLER: Objection. 18 THE WITNESS: I don't recall. 19 I'm going to have to see it. 20 QUESTIONS BY MR. TISI: 21 Q. Okay. Have you done any 22 studies in talc and ovarian cancer? 23 A. What do you mean by "studies"? 24 Q. Have you done any observational 25 studies on talc and ovarian cancer?</p>

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<p>1 A. I've reviewed the literature --</p> <p>2 Q. Have you done any studies?</p> <p>3 A. -- on the potential causal</p> <p>4 association between talcum powder and ovarian</p> <p>5 cancer. I've reviewed the literature.</p> <p>6 Q. Have you authored any studies</p> <p>7 on talc and ovarian cancer or designed any</p> <p>8 studies on talc and ovarian cancer?</p> <p>9 A. And I believe I told you no</p> <p>10 earlier on.</p> <p>11 Q. That was my question.</p> <p>12 Now, you mentioned in your</p> <p>13 report that there are seven hospital-based</p> <p>14 case-control studies examining the</p> <p>15 association between talc and ovarian cancer.</p> <p>16 A. Where did I say that?</p> <p>17 Q. It's in your chart, and you</p> <p>18 mentioned it several times today.</p> <p>19 MS. MILLER: You just said,</p> <p>20 this is in your report.</p> <p>21 THE WITNESS: You just said I</p> <p>22 wrote it in my report, so I just</p> <p>23 wanted to see where I said it.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. Are there not seven</p>	<p>1 the Rosenblatt study, Exhibit Number 40.</p> <p>2 Did you actually read this</p> <p>3 study?</p> <p>4 A. I did.</p> <p>5 Q. Good.</p> <p>6 Let's go, so we don't have to</p> <p>7 spend a lot of time rereading it.</p> <p>8 A. I haven't memorized it, though.</p> <p>9 Q. Okay. One of the authors of</p> <p>10 this study, if you'll notice, is a guy we</p> <p>11 mentioned a couple times today, Dr. Szklo.</p> <p>12 He's the second author.</p> <p>13 A. Szklo, yes.</p> <p>14 Q. Szklo.</p> <p>15 He's at the school. He's a</p> <p>16 full professor there.</p> <p>17 Have you ever said, you know,</p> <p>18 "Doctor, there's a study done at our school.</p> <p>19 What do you think about this relationship?</p> <p>20 You've published on it."</p> <p>21 Have you gone and talked to</p> <p>22 him?</p> <p>23 A. I have not.</p> <p>24 MS. MILLER: Objection.</p> <p>25 MR. LOCKE: Objection.</p>
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<p>1 observational -- seven hospital-based</p> <p>2 studies, Doctor?</p> <p>3 A. I have a chart here that has</p> <p>4 seven hospital-based case-control studies.</p> <p>5 Q. Okay. And one of them we just</p> <p>6 talked about, it was Rosenblatt, and it was</p> <p>7 done here at Johns Hopkins, was it not?</p> <p>8 A. I don't specifically recall.</p> <p>9 Q. Well, actually, you mention</p> <p>10 that on page 14 of your report. Go to</p> <p>11 page 14 of your report.</p> <p>12 You say, "Rosenblatt is a 1992</p> <p>13 reported hospital-based study evaluating</p> <p>14 fiber exposure generally with fiber defined</p> <p>15 as asbestos talc or fiberglass, et cetera,</p> <p>16 done in Johns Hopkins Hospital."</p> <p>17 Do you see that?</p> <p>18 A. A little bit before my time,</p> <p>19 1981 to 1985 --</p> <p>20 Q. Right.</p> <p>21 A. -- at Johns Hopkins.</p> <p>22 (Merlo Exhibit 40 marked for</p> <p>23 identification.)</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. All right. I'm like to attach</p>	<p>1 MS. MILLER: Give us time to</p> <p>2 object, Doctor.</p> <p>3 THE WITNESS: Okay. Sorry.</p> <p>4 I did my own independent</p> <p>5 search, and I evaluated the body of</p> <p>6 medical evidence.</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. Now, if you go to -- I'm sorry.</p> <p>9 A. I did read this article, and I</p> <p>10 did see that -- recall now that I did see his</p> <p>11 name on there, but it did not interfere or</p> <p>12 cause me reflection to go talk to him about</p> <p>13 it because I was going to perform my own</p> <p>14 independent review.</p> <p>15 Q. Right.</p> <p>16 So you had on the chart -- on</p> <p>17 your chart, exhibit number -- do you have</p> <p>18 your chart in front of you? Exhibit 37?</p> <p>19 A. I have Exhibit 37, yes.</p> <p>20 Q. And I asked you before whether</p> <p>21 or not Rosenblatt was inconsistent with</p> <p>22 Cramer.</p> <p>23 Do you remember that?</p> <p>24 And you said yes?</p> <p>25 A. So if we're still -- which</p>

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<p>1 Rosenblatt, again, are we talking about?</p> <p>2 Because there are two Rosenblatts.</p> <p>3 Q. 1992.</p> <p>4 A. Rosenblatt '92. I got it.</p> <p>5 Q. And Cramer 1982.</p> <p>6 A. Got it.</p> <p>7 Q. And I asked you the question,</p> <p>8 and you said that they were inconsistent.</p> <p>9 Well, let's see what Dr. Szklo</p> <p>10 says about this.</p> <p>11 Now, just to be clear,</p> <p>12 Rosenblatt is a hospital-based case-control</p> <p>13 study?</p> <p>14 A. Rosenblatt was a hospital-based</p> <p>15 case-control study, yes, that's correct.</p> <p>16 Q. And Cramer was a</p> <p>17 population-based case-control study?</p> <p>18 A. Cramer 1982 was a</p> <p>19 population-based case-control study.</p> <p>20 Q. Now, first, if you go to the</p> <p>21 study itself, if you go to the third page,</p> <p>22 page 22.</p> <p>23 A. Page 22, yes.</p> <p>24 Q. It says -- actually, the second</p> <p>25 column it says, "We found an increased</p>	<p>1 A. -- an odds ratio of 1 --</p> <p>2 Q. Okay.</p> <p>3 A. -- which is null.</p> <p>4 Q. And when you have talc, it's</p> <p>5 1.7, and when you have it directly applied to</p> <p>6 sanitary napkins, it was 4.8 -- do you see</p> <p>7 that? -- which was statistically significant.</p> <p>8 A. Statistically significant with</p> <p>9 a confidence interval of 1.3 to 17.8, a very,</p> <p>10 very wide range, and with also a proportion</p> <p>11 of missing -- of cases and controls with</p> <p>12 missing exposure.</p> <p>13 Q. But then he says something that</p> <p>14 addresses your point directly. It says,</p> <p>15 "This is" -- and I'm going to read the whole</p> <p>16 paragraph.</p> <p>17 MS. MILLER: Tell us where you</p> <p>18 are.</p> <p>19 MR. TISI: Yeah. Second</p> <p>20 column. It's beginning with "we</p> <p>21 found" on page 22.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. "We found an increased relative</p> <p>24 risk, 4.8 for talc use on sanitary napkins,</p> <p>25 with a smaller effect for genital bath</p>
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<p>1 relative risk, 4.8, for talc use on sanitary</p> <p>2 napkins, with a smaller effect on genital</p> <p>3 bath talc exposure, relative risk 1.7."</p> <p>4 Do you see that?</p> <p>5 A. I do see that.</p> <p>6 Q. Can you tell me why it is you</p> <p>7 didn't refer to the talc on sanitary napkins'</p> <p>8 relative risk of 4.8, which was statistically</p> <p>9 significant?</p> <p>10 A. The point estimate that I took</p> <p>11 out of that was for genital talc exposure,</p> <p>12 which is a relative risk of 1.70.</p> <p>13 Q. All right. But genital talc</p> <p>14 exposure was defined as asbestos --</p> <p>15 asbestos -- I'm sorry, it was actually fiber</p> <p>16 exposure.</p> <p>17 In your report on page 15, you</p> <p>18 talk about it as being -- it's defined --</p> <p>19 A. Well, if you actually look at</p> <p>20 Table 3, the genital fiber use, yes/no, has</p> <p>21 an odds ratio of 1.0, and the 95 percent</p> <p>22 confidence interval is 0.2 to 4.0.</p> <p>23 So if we're just talking about</p> <p>24 genital fiber use, there's --</p> <p>25 Q. Okay.</p>	<p>1 exposure, 1.7."</p> <p>2 And that 1.7 was not</p> <p>3 statistically significant, correct?</p> <p>4 A. The 1.7 was not statistically</p> <p>5 significant.</p> <p>6 Q. Okay. He then says, "This is</p> <p>7 in accordance with the original finding of a</p> <p>8 significant increased risk for perineal talc</p> <p>9 exposure, relative risk 1.9, 95 percent</p> <p>10 confidence interval, 1.3 to 2.9, by Cramer,</p> <p>11 et al."</p> <p>12 And that's the Cramer article</p> <p>13 from 1982, correct?</p> <p>14 A. That's what it says.</p> <p>15 Q. Okay. And so he's saying his</p> <p>16 results are actually consistent with what</p> <p>17 Cramer found.</p> <p>18 A. But they're not.</p> <p>19 Q. Okay. But Dr. Szklo says that</p> <p>20 they are?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: If we're talking</p> <p>23 about consistency here between two</p> <p>24 studies and talking about statistical</p> <p>25 significance and consistency within</p>

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<p style="text-align: right;">Page 366</p> <p>1 statistical significance, they're not 2 consistent. 3 QUESTIONS BY MR. TISI: 4 Q. Okay. Because statistical 5 significance is never the test for 6 consistency, is it, Doctor? 7 And everybody from the 8 epidemiology textbooks to the American 9 Statistical Association says, don't do what 10 you did in this report, true? 11 MS. MILLER: Objection. 12 MR. LOCKE: Objection. 13 THE WITNESS: I don't even know 14 what that means, and I -- 15 QUESTIONS BY MR. TISI: 16 Q. Okay. 17 A. -- don't know what you mean by 18 everyone and -- 19 Q. Well, we're going to talk -- 20 A. -- who those different groups 21 are, so you'd have be very specific. 22 Q. We're going to be -- 23 A. It's a very big generalization. 24 Q. Well, you made a lot of 25 generalizations about what the epidemiology</p>	<p style="text-align: right;">Page 368</p> <p>1 talc fiber exposure may be associated with an 2 adverse event, but further study is needed." 3 Do you see that? 4 A. I do, and that's a very, very 5 general statement. There's a "suggest," 6 there's a "may," there's an "associated," 7 there's an "adverse effect." I don't even 8 know what that means. 9 Q. He never said it was 10 inconsistent, did he? He said, in fact, his 11 study -- this study is in accordance with the 12 original study. 13 MS. MILLER: Objection. 14 THE WITNESS: This statement 15 right here is not talking about -- is 16 not talking about consistency, this 17 results of our study. I don't know 18 why that has anything to do with 19 consistency. 20 QUESTIONS BY MR. TISI: 21 Q. Okay. Well, let's go to the 22 paragraph that does. 23 It says above, "We found an 24 increased, 4.8 for talc use on sanitary 25 napkins, with a smaller effect for genital</p>
<p style="text-align: right;">Page 367</p> <p>1 community thinks. 2 MR. LOCKE: Objection. 3 QUESTIONS BY MR. TISI: 4 Q. So I'm talking to you about 5 epidemiology textbooks. The American 6 Statistical Association says, you don't do 7 what you did here. 8 MS. MILLER: Objection. 9 MR. LOCKE: Objection. 10 QUESTIONS BY MR. TISI: 11 Q. Let me ask you this. He says 12 below, "The results of our study suggest that 13 genital talc fiber exposure may be associated 14 with an adverse event, but further study is 15 needed to determine if this relationship is 16 causal in nature from 1990 -- this 1992 17 study." 18 Correct? 19 A. Where are you reading that? 20 Q. The paragraph below. It says, 21 "The results of our study." Two paragraphs 22 down. 23 A. Okay. 24 Q. Okay. It says, "The results of 25 our study and others suggest that genital</p>	<p style="text-align: right;">Page 369</p> <p>1 bath talc exposure, relative risk, 1.7. This 2 is in accordance with the original finding of 3 a significant increased risk for perineal 4 talc exposure by Cramer, et al. Preliminary 5 findings from a Chinese talc study also 6 suggest the application of talc-containing 7 dusting powder and the risk of epithelial 8 ovarian cancer relative risk to be 1.9, with 9 a confidence interval of 1.1 to 13.8," which 10 is the Chen study on your list. "A 11 nonsignificant effect for genital talc 12 exposure on genital sanitary napkins or 13 underwear was detected in a study by Hartge, 14 relative risk 2.5, which was not 15 statistically significant. Whittemore, et 16 al., detected an increased relative risk 1.4, 17 P value greater than .05, for perineal 18 exposure. In a study of borderline ovarian 19 tumors, the increased risk was also observed 20 with talc exposure use on sanitary napkins, 21 relative risk 1.9 with a confidence interval 22 of .9 to 6.9." 23 This paragraph says all these 24 studies show an increased risk, true? 25 Including the last one that says an increased</p>



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<p>1 risk was observed in a nonstatistically 2 significant study. 3 MS. MILLER: Objection. 4 MR. LOCKE: Objection. 5 THE WITNESS: This paragraph 6 does not say that there's an increased 7 risk in all these studies. 8 This paragraph says -- this 9 paragraph highlights that some studies 10 are statistically significant and 11 others are nonstatistically 12 significant. And that is not 13 consistent. 14 QUESTIONS BY MR. TISI: 15 Q. They say these are -- these 16 studies are in accordance, and you're saying 17 that that's inconsistent? 18 MS. MILLER: Objection. 19 THE WITNESS: That's not what 20 it says. 21 QUESTIONS BY MR. TISI: 22 Q. It says this study is in 23 accordance with the original finding of a 24 significant -- a significant increased risk 25 for perineal talc exposure, true? Does it</p>	<p>1 statement. It says "suggests," "may," 2 "associated adverse effect." I don't even 3 know what the adverse effect he's talking 4 about is. 5 Q. Well, how about the last -- 6 let's talk about the last paragraph. 7 "In summary" -- 8 MS. MILLER: The last paragraph 9 of what -- 10 MR. TISI: Of the study. 11 MS. MILLER: Oh, okay. 12 QUESTIONS BY MR. TISI: 13 Q. "In summary, our study shows 14 that the development of ovarian cancer may 15 be -- may be associated with genital fiber 16 exposure, especially talc on sanitary 17 napkins." 18 Do you see that? 19 A. I do. 20 And then it says, "Given its 21 small sample size and the potential selection 22 bias stemming from including patients in only 23 one hospital, further research needs to be 24 performed in order to confirm our findings." 25 And that is the importance of</p>
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<p>1 not say that? 2 A. And what that sentence is 3 referring to is the sentence before that, 4 which is talking about an increased relative 5 risk for talc use on sanitary napkins, and 6 that's it. It's not in accordance -- 7 Q. No, that's not true. 8 A. It is. 9 Q. It says with a smaller effect 10 for genital bath talc exposure, relative risk 11 1.7. It includes both, does it not? 12 A. That relative risk is not 13 statistically significant. If they're 14 talking about the point estimate being over 15 1, that may be true, but this paragraph does 16 not say anything about consistency within 17 these studies. In fact, this highlights 18 inconsistency between all of these studies. 19 Q. Okay. Well, and so 20 Dr. Moyses -- Dr. Szklo is wrong when he says 21 this: "The results of our study and others 22 suggest that genital fiber exposure may be 23 associated with an adverse effect." 24 He's wrong when he says that? 25 A. That is such a general</p>	<p>1 consistency. And that first paragraph that 2 you highlighted demonstrates the lack of 3 consistency. 4 Q. Doctor, he's saying that this 5 study is further support of the hypothesis, 6 additional study needs to be done, but that 7 this shows that the development of ovarian 8 cancer may be associated with genital fiber 9 exposure. That's what he says. I'm reading 10 directly from the report. 11 MR. LOCKE: Objection. 12 THE WITNESS: And where are you 13 reading that? 14 QUESTIONS BY MR. TISI: 15 Q. "In summary, our study shows 16 that the development of ovarian cancer may be 17 associated with genital fiber exposure, 18 especially talc on sanitary napkins and 19 exposure to fibers in relatives." 20 He does say that, correct? 21 MS. MILLER: Objection. 22 THE WITNESS: He says, "Our 23 study shows that the development of 24 ovarian cancer may be associated." 25 "May be associated."</p>



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<p style="text-align: right;">Page 374</p> <p>1 And then he also says -- and  2 I'll say this again -- "Given its  3 small sample size and the potential  4 for selection bias" --  5 QUESTIONS BY MR. TISI:  6 Q. And he doesn't say this is  7 inconsistent, does he? He doesn't say, our  8 studies are opposite to. He doesn't say, our  9 studies are inconsistent with, does he?  10 MR. LOCKE: Objection.  11 MS. MILLER: Objection.  12 THE WITNESS: He doesn't say  13 they're inconsistent. He doesn't say  14 either. But they are inconsistent  15 with each other, because some are  16 showing a statistical significance and  17 some are not.  18 (Merlo Exhibit 41 marked for  19 identification.)  20 QUESTIONS BY MR. TISI:  21 Q. Let's go to another one.  22 A. They're inconsistent.  23 Q. Let's go to another one.  24 There's another one that you refer to. It's  25 the Tzonou study from Greece, the Tzonou</p>	<p style="text-align: right;">Page 376</p> <p>1 A. Can you just show me? I'm  2 sorry, I just didn't know where that was.  3 Okay.  4 Q. Does it not say, "The result of  5 the present study do not support the  6 association between talc and ovarian cancer  7 but given the overlapping range of the  8 confidence intervals, they are not  9 incompatible"?  10 MR. LOCKE: Objection.  11 THE WITNESS: I do see that  12 sentence, but I'm just trying to  13 figure out where that -- that that is  14 reference to.  15 QUESTIONS BY MR. TISI:  16 Q. Okay. Was it important to you  17 to figure out what that doctor meant by that?  18 The overlapping confidence intervals is  19 consistency, is it not?  20 MR. LOCKE: Objection.  21 THE WITNESS: I don't know what  22 you mean by overlapping confidence  23 intervals.  24 QUESTIONS BY MR. TISI:  25 Q. If confidence intervals overlap</p>
<p style="text-align: right;">Page 375</p> <p>1 study. I'm going to show you this one. This  2 is one you also read.  3 And this is another  4 hospital-based study, correct?  5 And this is the one on your  6 chart --  7 MS. MILLER: I'm sorry, I took  8 yours.  9 MR. TISI: I'm sorry.  10 QUESTIONS BY MR. TISI:  11 Q. This is the one on your chart  12 that has a 1.05 with a confidence interval of  13 .28 to 3.98.  14 Do you see that?  15 A. I see on my chart 1.05, with a  16 95 confidence interval of .28 to 3.98.  17 Q. Let's look at what these  18 doctors say about this relationship. If you  19 go to page 409, second column, it says, "The  20 results of the present study do not support  21 an association between talc and ovarian  22 cancer but given the overlapping range in the  23 confidence intervals, they are not  24 incompatible with it."  25 True?</p>	<p style="text-align: right;">Page 377</p> <p>1 between studies and -- let's say at 1.2,  2 those are consistent. The confidence  3 intervals are consistent, correct?  4 MS. MILLER: Objection.  5 THE WITNESS: It depends. It  6 depends if you have three, eight, ten  7 studies that show 1.2, 1.3, their  8 confidence intervals overlap and those  9 are all statistically significant,  10 then those would be consistent.  11 However, if you have a point  12 estimate -- if you have several  13 studies that have point estimates of  14 1.2, 1.3, those are statistically  15 significant, and you have several  16 studies that have similar point  17 estimates but they're not  18 statistically significant, no, they  19 would be inconsistent with each other.  20 QUESTIONS BY MR. TISI:  21 Q. Even though the confidence  22 intervals overlap?  23 A. That's not really how you  24 approach consistency, in just looking at the  25 confidence intervals and seeing if they</p>

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<p style="text-align: right;">Page 378</p> <p>1 overlap.</p> <p>2 Because the two studies, if</p> <p>3 we're talking about a consistent set, the</p> <p>4 studies would be statistically significant,</p> <p>5 and that would point towards consistency.</p> <p>6 Q. I'm going to like to show</p> <p>7 you -- have you seen a meta-analysis of the</p> <p>8 hospital-based studies at all?</p> <p>9 A. I did review some</p> <p>10 meta-analyses.</p> <p>11 Q. Did you review the</p> <p>12 meta-analyses of the hospital-based studies?</p> <p>13 A. I would have to look back at my</p> <p>14 report and see --</p> <p>15 Q. Let me see if I can show you</p> <p>16 the Berge study.</p> <p>17 A. -- which -- which had the</p> <p>18 hospital-based studies.</p> <p>19 Q. Let me show you the Berge</p> <p>20 study, which you've actually seen, correct?</p> <p>21 MS. MILLER: Can you show us,</p> <p>22 too?</p> <p>23 THE WITNESS: Okay.</p> <p>24 (Merlo Exhibit 48 marked for</p> <p>25 identification.)</p>	<p style="text-align: right;">Page 380</p> <p>1 significant for the hospital-based studies,</p> <p>2 correct?</p> <p>3 A. For -- that's what that</p> <p>4 suggests for those six studies.</p> <p>5 Q. Now, Doctor, just while we're</p> <p>6 at it here, and we're going to talk about</p> <p>7 the -- by the way, you didn't reference that</p> <p>8 in your report, did you, that there was a</p> <p>9 meta-analysis of the hospital-based studies</p> <p>10 that showed a statistically significant</p> <p>11 increased risk?</p> <p>12 MR. LOCKE: Objection.</p> <p>13 THE WITNESS: Can you ask that</p> <p>14 one more time?</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. Yes.</p> <p>17 You didn't note that there was</p> <p>18 a meta-analysis of the hospital-based studies</p> <p>19 in the Berge study that showed a</p> <p>20 statistically significant increased risk, did</p> <p>21 you?</p> <p>22 MR. LOCKE: Objection.</p> <p>23 THE WITNESS: In the</p> <p>24 meta-analysis done by Berge, I did not</p> <p>25 reference that hospital-based</p>
<p style="text-align: right;">Page 379</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. If you go to the table on</p> <p>3 page 6 of 15.</p> <p>4 Do you see they have</p> <p>5 case-control studies and they have</p> <p>6 hospital-based control studies?</p> <p>7 Do you see that?</p> <p>8 A. I do see that.</p> <p>9 Q. Okay. See the relative risk of</p> <p>10 1.34?</p> <p>11 A. I do see 1.34.</p> <p>12 Q. See the confidence interval</p> <p>13 greater than 1, 1.16 to 1.51?</p> <p>14 A. I see 1.16 to 1.51.</p> <p>15 Q. What does that tell you,</p> <p>16 Doctor?</p> <p>17 MR. LOCKE: Objection.</p> <p>18 THE WITNESS: Well, it tells me</p> <p>19 that looking at these six case-control</p> <p>20 studies, the relative risk in however</p> <p>21 they lump these together was a 1.34,</p> <p>22 with a 95 percent confidence interval</p> <p>23 of 1.16 to 1.5 -- sorry, 1.51.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. And that's statistically</p>	<p style="text-align: right;">Page 381</p> <p>1 case-control study table right there.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. And that showed an increased</p> <p>4 risk?</p> <p>5 A. I would have to go through and</p> <p>6 look at the papers that were pulled for that</p> <p>7 because I have seven on my list, and there's</p> <p>8 six there.</p> <p>9 Q. Okay. But, of course, this</p> <p>10 study was published and yours wasn't. Your</p> <p>11 report has not been?</p> <p>12 MR. LOCKE: Objection.</p> <p>13 MS. MILLER: Objection.</p> <p>14 THE WITNESS: I didn't do a</p> <p>15 meta-analysis. I just gave a summary</p> <p>16 statement of the available</p> <p>17 hospital-based case controls, and</p> <p>18 they're all not statistically</p> <p>19 significant.</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. Right.</p> <p>22 And -- but when you combine</p> <p>23 them, because they were not powered to do it,</p> <p>24 they were small studies, because the</p> <p>25 confidence intervals were large -- you</p>

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<p style="text-align: right;">Page 382</p> <p>1 indicated that before. When you combine 2 them, you increase the power, right? 3 MR. LOCKE: Objection. 4 MS. MILLER: Objection. 5 THE WITNESS: You can -- 6 QUESTIONS BY MR. TISI: 7 Q. Okay. 8 A. -- if the studies looked at the 9 same thing. 10 Q. Right. 11 A. If they looked at the same 12 measure of exposure. 13 Q. So when they combine them, it 14 increased the power. They show a 15 statistically significant results in the 16 Berge study, correct? 17 MS. MILLER: Objection. He 18 specifically said something different. 19 MR. TISI: You get to cross. 20 THE WITNESS: If, in fact, the 21 studies are measuring the same aspect 22 of the exposure, which there are 23 varying measures of exposure with -- 24 in all of the case-control studies, if 25 they're measuring the same thing, then</p>	<p style="text-align: right;">Page 384</p> <p>1 THE WITNESS: And I would have 2 to go through and see why there's only 3 six there and see what the measure of 4 risk was and whether or not that was 5 appropriate to even combine those. 6 QUESTIONS BY MR. TISI: 7 Q. Okay. But you didn't do that, 8 and you didn't address this in your report? 9 MR. LOCKE: Objection. 10 THE WITNESS: So in looking at 11 this table now, I'm looking at the 12 hospital-based case-control studies, 13 and there's six of them, and the 14 relative risk is as you say. But 15 there is significant heterogeneity 16 within the studies, and so it may not 17 be appropriate to lump all of those 18 together. 19 And I believe that the authors 20 concluded that because of 21 heterogeneity, it did not support a 22 causal interpretation of the 23 association. 24 QUESTIONS BY MR. TISI: 25 Q. Doctor, let me ask you this:</p>
<p style="text-align: right;">Page 383</p> <p>1 it does add -- it does add more study 2 subjects, which increases -- it does 3 add more study subjects. 4 QUESTIONS BY MR. TISI: 5 Q. And it does increase the power? 6 MR. LOCKE: Objection. 7 QUESTIONS BY MR. TISI: 8 Q. To detect an association, 9 correct? 10 MR. LOCKE: Objection. 11 MS. MILLER: Objection. 12 THE WITNESS: That's not really 13 what power is for. Power is to say 14 that if you don't detect a certain 15 association, that you're not wrong 16 about that. That's what power's for. 17 QUESTIONS BY MR. TISI: 18 Q. Well, the original studies did 19 not detect a statistically significant 20 result, but when you combine them, they did, 21 true? 22 MS. MILLER: Objection. 23 MR. LOCKE: Objection. 24 MS. MILLER: No, that's not 25 what he said.</p>	<p style="text-align: right;">Page 385</p> <p>1 It also says at the top -- and if you look at 2 the abstract -- actually, the -- and I'll 3 represent to you that this study was actually 4 amended. The original study was amended a 5 year later, so this is the amended study. 6 It says, "This meta-analysis 7 resulted in a weak" -- second to the last 8 sentence -- "weak but statistically 9 significant association between genital talc 10 use and ovarian cancer, which appears to be 11 limited to serous carcinoma with the 12 suggestion of a dose response." 13 Do you see that? 14 MR. LOCKE: Objection. 15 THE WITNESS: That's in the 16 abstract? 17 QUESTIONS BY MR. TISI: 18 Q. Yes. 19 A. Can you read that again? 20 Q. Yeah. 21 Second to the last sentence. 22 It says, "The meta-analysis results in a weak 23 but statistically significant association 24 between genital talc -- genital use of talc 25 and ovarian cancer, which appears to be</p>

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<p>1 limited to serous carcinoma and suggests -- 2 with the suggestion of dose response." 3 Did I read that correctly? 4 A. You read that correctly. 5 Q. You don't note that in your 6 report, do you? 7 MR. LOCKE: Objection. 8 THE WITNESS: But the authors 9 also say in their concluding sentence, 10 "Several aspects of our study, 11 including heterogeneity of results 12 between case-control and cohort 13 studies, however, do not support a 14 causal interpretation of the 15 association." 16 QUESTIONS BY MR. TISI: 17 Q. I understand, Doctor. 18 I asked you whether I read the 19 prior sentence correctly about a dose 20 response, and you didn't address that in your 21 report, did you not? 22 MR. LOCKE: Objection. 23 MS. MILLER: Objection. 24 THE WITNESS: Well, let's look 25 at dose response then.</p>	<p>1 QUESTIONS BY MR. TISI: 2 Q. The question is whether you did 3 or you didn't. 4 MS. MILLER: Please don't 5 interrupt the witness. 6 MR. TISI: No, he needs to 7 answer my questions. 8 MS. MILLER: He's answering 9 your questions as fully as he can -- 10 MR. TISI: My question is, I 11 know you -- 12 MS. MILLER: And now you're 13 interrupting me. 14 MR. TISI: I know you -- well, 15 because you're coaching. 16 QUESTIONS BY MR. TISI: 17 Q. Doctor, I know you discussed 18 the -- 19 MR. TISI: Your laughing is 20 really, really overwhelming. 21 MS. MILLER: You just accused 22 me of coaching the witness for saying 23 "please don't interrupt him." 24 MR. TISI: You are totally 25 coaching the witness. Don't interrupt</p>
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<p>1 QUESTIONS BY MR. TISI: 2 Q. Let's look at -- yeah. You 3 didn't address it. I looked for it. I 4 didn't find it. 5 A. The only reason I'm looking at 6 this is because I did address dose response, 7 and I looked at all of the dose response 8 within all of the studies available. And in 9 order for Berge to talk about dose response, 10 the studies that involve a dose response have 11 to go in there. 12 And aside from one study, which 13 is Wu 2015, there is no dose response. 14 There's random curves, there's convex curves, 15 convey curves, in Booth, Wong, Cook, Mills, 16 Merritt, Gertig, Cramer, in all of those. So 17 actually I did. 18 Q. Okay. My question is -- 19 A. And there's no dose response. 20 Q. Did you address Berge's 21 analysis of that issue? 22 MS. MILLER: Objection. 23 THE WITNESS: There's no need 24 to because -- 25</p>	<p>1 him. He was saying X, Y and Z. It's 2 coaching. 3 MS. MILLER: Excuse me? I 4 said, "Please don't interrupt the 5 witness." 6 Where did I say he was saying 7 X, Y and Z? 8 QUESTIONS BY MR. TISI: 9 Q. Doctor -- 10 MS. MILLER: What are you even 11 talking about? 12 QUESTIONS BY MR. TISI: 13 Q. Doctor, did you address the 14 analysis done by Berge on the dose response 15 issue in your report? 16 You may have done the 17 underlying studies, but did you discuss 18 Berge's? 19 MR. LOCKE: Objection. 20 THE WITNESS: I actually am 21 trying to find where the -- where the 22 dose response is even discussed in 23 Berge. 24 QUESTIONS BY MR. TISI: 25 Q. Okay. I can help you with</p>

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<p>1 that.</p> <p>2 Have you actually seen this?</p> <p>3 This -- because there are two Berge</p> <p>4 publications. There was the original and</p> <p>5 there was an amended one. This is the</p> <p>6 amended one.</p> <p>7 Did counsel provide you with</p> <p>8 the amended one?</p> <p>9 A. Counsel didn't provide me with</p> <p>10 any articles.</p> <p>11 Q. Okay.</p> <p>12 A. I looked them up myself.</p> <p>13 Q. Did you find this one?</p> <p>14 A. Again, I don't have these</p> <p>15 memorized, so I don't know which is the first</p> <p>16 one or which is the second one.</p> <p>17 Q. This is the second one.</p> <p>18 MS. MILLER: Is there a</p> <p>19 question pending? I'm so sorry, I</p> <p>20 lost it.</p> <p>21 MR. TISI: Yes.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Did you see this -- have you --</p> <p>24 will you see the second -- the second Berge</p> <p>25 study?</p>	<p>1 it'll be.</p> <p>2 THE WITNESS: I don't know how</p> <p>3 you can say that this -- that I</p> <p>4 didn't -- that I looked at this one or</p> <p>5 the other one.</p> <p>6 MR. TISI: It'll be what it'll</p> <p>7 be. I will compare the citation, and</p> <p>8 it'll either be the one you looked at</p> <p>9 or not. Let's move on.</p> <p>10 THE WITNESS: Well, we can</p> <p>11 compare it right now.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. I want to go -- Doctor --</p> <p>14 A. I'm going to look to compare it</p> <p>15 right now.</p> <p>16 Q. Well, then you can do it off</p> <p>17 the record. I'm not doing it on the record.</p> <p>18 A. Well, then you can't say</p> <p>19 that -- that you can just assume that --</p> <p>20 Q. I'm not --</p> <p>21 A. -- I saw the first one and</p> <p>22 didn't see the second one.</p> <p>23 Q. Doctor, I'll look it up. You</p> <p>24 have the citation in the back of your</p> <p>25 references. I'll just look it up.</p>
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<p>1 A. I may have had the second one</p> <p>2 or the first one. I don't know.</p> <p>3 Q. Okay.</p> <p>4 A. Because it's not --</p> <p>5 MS. MILLER: Can we check his</p> <p>6 references?</p> <p>7 MR. TISI: Well, no, I think</p> <p>8 the record will be -- the record will</p> <p>9 be that he didn't, so we'll just go</p> <p>10 on.</p> <p>11 THE WITNESS: No, I'm not</p> <p>12 saying that, because I --</p> <p>13 MR. TISI: No, I think the</p> <p>14 record will be that the study that you</p> <p>15 looked at was the original Berge study</p> <p>16 but not the amended one.</p> <p>17 THE WITNESS: Why do you say</p> <p>18 that?</p> <p>19 MR. TISI: Because you have a</p> <p>20 citation to it with a year and the</p> <p>21 publication.</p> <p>22 MS. MILLER: And the citation</p> <p>23 is to 2018, and this year is this?</p> <p>24 THE WITNESS: And this is 2018.</p> <p>25 MR. TISI: Okay. It'll be what</p>	<p>1 If you go to your chart here,</p> <p>2 exhibit -- that we marked as Exhibit</p> <p>3 Number 37 -- it's right in front of you,</p> <p>4 sir -- would you agree with me that of all</p> <p>5 the studies of whatever design, other than</p> <p>6 Hartge 1983, Hartge and Stewart 1994, and</p> <p>7 Gonzalez 2016, all -- every single one of</p> <p>8 these risk ratios or relative risks or hazard</p> <p>9 ratios is greater than 1?</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: The point</p> <p>12 estimates in this -- in this chart,</p> <p>13 Hartge 1983, Hartge Stewart '94, and</p> <p>14 Gonzales are all below 1. The others</p> <p>15 are -- the point estimates are above</p> <p>16 1.</p> <p>17 QUESTIONS BY MR. TISI:</p> <p>18 Q. Okay. And so of the</p> <p>19 30-some-odd studies, all of them have -- all</p> <p>20 of these studies, 30 of 33 or whatever the</p> <p>21 number happens to be, other than three have a</p> <p>22 risk ratio, relative risk or hazard ratio,</p> <p>23 greater than 1?</p> <p>24 A. A point estimate greater than</p> <p>25 1.</p>

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<p style="text-align: right;">Page 394</p> <p>1 Q. Greater than 1. 2 Would you look at the 3 confidence interval of the ones that have a 4 greater -- a point estimate greater than 1? 5 Would you agree that the 6 confidence intervals overlap for every one of 7 those studies at 1.2? 8 MS. MILLER: Objection. 9 THE WITNESS: I would have to 10 use a calculator to do that. 11 QUESTIONS BY MR. TISI: 12 Q. Well, all you have to do is 13 look at the -- all you have to look at is the 14 confidence interval, right? The confidence 15 interval? If it overlaps 1.2, then it's -- 16 then they're overlapping, right? 17 A. It's not how we use a 18 confidence interval, but if that's what -- if 19 that's the number that you want to say, but 20 that's not how -- 21 Q. They're all -- every single one 22 of these confidence intervals, with the 23 exception of the three that I just talked 24 about, overlap at 1.2. 25 A. For the purpose of this</p>	<p style="text-align: right;">Page 396</p> <p>1 every one, but they -- most of them do. 2 In fact, even if you look at 3 the cohort studies, with the exception of 4 Gonzalez, they include 1.25. 5 A. Okay. 6 Q. Is that true? 7 A. It looks like it, based on this 8 chart. 9 Q. Now, I provided Dr. Ballman -- 10 have you seen Dr. Ballman's exhibits? 11 A. Yes. 12 Q. Okay. I provided her with a 13 copy of your chart, which I will have marked 14 as Exhibit 42. Since you had time to look at 15 it, I'm going to ask you whether you agree 16 with her or not. 17 (Merlo Exhibit 42 marked for 18 identification.) 19 QUESTIONS BY MR. TISI: 20 Q. I asked her to highlight, to 21 circle, every -- I asked her to highlight 22 every -- in red, in pink, every result that 23 was greater than 1.0, and she did. 24 Do you see that? 25 MS. MILLER: Objection.</p>
<p style="text-align: right;">Page 395</p> <p>1 exercise, looking down that column, 2 95 percent confidence interval, and you want 3 me to say whether or not there's overlap at 4 1.2? 5 Q. Uh-huh. 6 A. And what was the other 7 qualification? 8 Q. None. 9 The vast majority of these 10 confidence intervals overlap at 1.2, true? 11 A. 1.2 is included in many of 12 these. 13 Q. The vast majority -- in fact 14 every one, with the exception of three that I 15 just mentioned? 16 A. Well, Cramer 1982 is 1.27. Wu 17 2015 is 1.27. 18 Q. Right. 19 A. That doesn't include 1.2. 20 Q. Okay. Okay. 1.2 or above. 21 A. Okay. 22 Q. Is that true? 23 A. That is true for that column. 24 Q. Okay. And in fact, most of 25 them have -- overlap at 1.25, correct? Not</p>	<p style="text-align: right;">Page 397</p> <p>1 MR. LOCKE: Objection. 2 THE WITNESS: What -- you're -- 3 what did she highlight? 4 QUESTIONS BY MR. TISI: 5 Q. Every result that had a risk 6 ratio greater than 1.0, and she highlighted 7 that in pink. 8 A. And you're talking about the 9 point estimate? 10 Q. The point estimate, correct. 11 MR. LOCKE: I'm going to object 12 for the same reasons we did during her 13 deposition. 14 MR. TISI: Okay. 15 QUESTIONS BY MR. TISI: 16 Q. Do you see that? 17 A. That's what it looks like. 18 Q. Okay. And she circled every 19 point estimate -- she circled every 20 confidence interval that included 1.2, which 21 is a 20 percent increase, correct? 22 MR. LOCKE: Same objection. 23 MS. MILLER: Objection. 24 QUESTIONS BY MR. TISI: 25 Q. Do you see that, and do you</p>

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<p style="text-align: right;">Page 398</p> <p>1 disagree with that?</p> <p>2 MS. MILLER: I'm going to</p> <p>3 object. I don't understand how you</p> <p>4 disagree with circling, and also --</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. Do you --</p> <p>7 MS. MILLER: -- this is kind of</p> <p>8 illegible.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Do you agree --</p> <p>11 MR. TISI: It's very legible to</p> <p>12 me, Counsel, but you can coach your</p> <p>13 witness if you'd like. I can read it</p> <p>14 very carefully. Very well.</p> <p>15 THE WITNESS: I see circles in</p> <p>16 the 95 percent confidence interval,</p> <p>17 and if you're asking if those circles</p> <p>18 include a range that includes 1.2 in</p> <p>19 that 95 percent confidence interval,</p> <p>20 that's what it appears to show.</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. And then I asked her to</p> <p>23 highlight in blue those that included 1.25,</p> <p>24 and she did that as well.</p> <p>25 Do you see that?</p>	<p style="text-align: right;">Page 400</p> <p>1 she appears to have done what you've</p> <p>2 asked her to do --</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. Okay.</p> <p>5 A. -- and circled.</p> <p>6 Q. And if asked to do the same</p> <p>7 thing, you would have done the same circling</p> <p>8 and the same highlighting?</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: If you asked me</p> <p>11 the same questions, it appears that</p> <p>12 she followed your directions</p> <p>13 appropriately.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Okay. Now, I'm going to show</p> <p>16 you what -- a textbook. It's already been</p> <p>17 marked as Exhibit Number 32.</p> <p>18 Can you pull that out, please?</p> <p>19 That's the Rothman textbook.</p> <p>20 A. 32?</p> <p>21 Q. Uh-huh. I have another copy in</p> <p>22 case anybody wants it because I don't really</p> <p>23 need paper. You can have it if you'd like.</p> <p>24 MS. MILLER: Okay. Instead of</p> <p>25 making us go through our pile.</p>
<p style="text-align: right;">Page 399</p> <p>1 MR. LOCKE: Objection.</p> <p>2 MS. MILLER: Objection.</p> <p>3 THE WITNESS: The blue is a</p> <p>4 little bit difficult to make out.</p> <p>5 There's purple.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. Well, purple is the -- it's</p> <p>8 blue and red. We didn't use a purple marker.</p> <p>9 A. And so what was the question?</p> <p>10 Q. Those were the ones that</p> <p>11 included 1.25 in the confidence interval.</p> <p>12 A. So it looks like this exercise</p> <p>13 does have a blue mark to those values that</p> <p>14 would include a 1.25 within the confidence</p> <p>15 interval.</p> <p>16 Q. And so in terms of we can</p> <p>17 disagree with the significance of that, you</p> <p>18 agree that with the interpretation that she</p> <p>19 had about risk ratios greater than 1, the</p> <p>20 ones that are greater than 1.2 -- or they</p> <p>21 included 1.2 and the ones that included 1.25?</p> <p>22 MS. MILLER: Objection.</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: For the purposes</p> <p>25 of you asking her what to highlight,</p>	<p style="text-align: right;">Page 401</p> <p>1 Thanks.</p> <p>2 MR. TISI: Yeah.</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. Do you have it in front of you?</p> <p>5 A. I have Modern Epidemiology.</p> <p>6 Q. Okay. If you look at the</p> <p>7 consistency prong -- we've looked at the</p> <p>8 strength prong before -- and it's on page 26</p> <p>9 of 30.</p> <p>10 A. Okay.</p> <p>11 Q. Okay. And I'm going to read</p> <p>12 the paragraph and see whether you agree with</p> <p>13 it or not.</p> <p>14 In this textbook Dr. Rothman</p> <p>15 says --</p> <p>16 A. I'm sorry, where are you</p> <p>17 reading from?</p> <p>18 Q. The second paragraph under</p> <p>19 Consistency. This is the consistency prong.</p> <p>20 "One mistake in implementing</p> <p>21 the consistency" --</p> <p>22 A. But where is this in the paper?</p> <p>23 I'm not seeing it. I see the second</p> <p>24 paragraph.</p> <p>25 Q. "One mistake." It says -- it</p>

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<p style="text-align: right;">Page 402</p> <p>1 starts with "one mistake."  2 Do you see it?  3 A. I see it now.  4 Q. Okay. "One mistake in  5 implementing the consistency criterion is so  6 common it deserves special mention. It is  7 sometimes claimed that a literature or set of  8 results is inconsistent simply because some  9 results are statistically significant and  10 some are not. This sort of evaluation is  11 completely fallacious, even if one accepts  12 the use of statistical -- the use of  13 significance testing methods."  14 Did I read that correctly?  15 MR. LOCKE: Objection.  16 MS. MILLER: Objection.  17 MR. LOCKE: And to the  18 characterization of this as a  19 textbook.  20 THE WITNESS: I see that  21 statement on this page.  22 QUESTIONS BY MR. TISI:  23 Q. You can pull the textbook out  24 so I don't have to, like, deal with that kind  25 of objection.</p>	<p style="text-align: right;">Page 404</p> <p>1 this instance where there are several  2 different kinds of study designs -- there's  3 consistency within study results. There's  4 consistency within hospital-based  5 case-controls. There's consistency in  6 nonsignificant -- nonsignificant results.  7 There's inconsistency in  8 population-based case-control studies where  9 some showed statistical significance, some  10 don't. There's also consistency within  11 cohort studies where there's a consistent  12 nonstatistically significance.  13 So there's consistency and  14 there's inconsistency. And just to divide it  15 up simply the way that Dr. Rothman says here  16 is too general because there are very  17 specific instances that need to be considered  18 before just agreeing or disagreeing to that  19 statement.  20 (Merlo Exhibit 43 marked for  21 identification.)  22 QUESTIONS BY MR. TISI:  23 Q. Okay. Let me look at Dr. --  24 what Dr. Oleckno says about it. Here's  25 Exhibit Number 43, which is also from the</p>
<p style="text-align: right;">Page 403</p> <p>1 MR. LOCKE: Well, it's a  2 portion of a book.  3 MR. TISI: Okay. Okay, Tom.  4 QUESTIONS BY MR. TISI:  5 Q. The chapter in a textbook.  6 That's exactly what you did, right?  7 A. I'm sorry?  8 Q. Do you agree with that  9 statement?  10 A. Do I agree with the statement?  11 Q. "One mistake in implementing  12 the consistency criterion is so common that  13 it deserves special attention. It is  14 sometimes claimed that a literature or set of  15 results is inconsistent simply because some  16 results are statistically significant and  17 some are not. That sort of evaluation is  18 completely fallacious, even if one accepts  19 the use of significance testing methods."  20 Did I read that correctly?  21 A. Yes, you did.  22 Q. Do you agree with that?  23 A. I would say it depends, and  24 I'll tell you why. Because it's a very  25 general statement. And if we're talking in</p>	<p style="text-align: right;">Page 405</p> <p>1 Oleckno textbook that you referred to in your  2 report.  3 And in the chapter --  4 MS. MILLER: This appears to be  5 pages 131, 173 and 174 --  6 MR. TISI: Correct.  7 MS. MILLER: -- so I'm going to  8 have the same objection.  9 MR. TISI: Fine.  10 MS. MILLER: This just pulls  11 things out of context rather than  12 including an inherent thing. I don't  13 know --  14 MR. TISI: I know you don't  15 know.  16 MS. MILLER: -- what's between  17 pages 131 --  18 MR. TISI: I know you don't  19 know, Counsel.  20 MS. MILLER: -- and 173 --  21 MR. TISI: Objection.  22 MS. MILLER: -- and what occurs  23 after page 175.  24 MR. TISI: "Objection" is fine.  25 THE WITNESS: Can I take a</p>

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<p>1 favor?</p> <p>2 MR. TISI: Yeah.</p> <p>3 THE WITNESS: Can we take a</p> <p>4 little -- I just need to use the</p> <p>5 restroom.</p> <p>6 MR. TISI: Absolutely.</p> <p>7 THE WITNESS: Would that be</p> <p>8 okay?</p> <p>9 MR. TISI: Absolutely.</p> <p>10 THE WITNESS: All right.</p> <p>11 Thanks.</p> <p>12 VIDEOGRAPHER: The time is</p> <p>13 4:20 p.m., and we're going off the</p> <p>14 record.</p> <p>15 (Off the record at 4:20 p.m.)</p> <p>16 VIDEOGRAPHER: The time is</p> <p>17 4:32 p.m., and we are back on the</p> <p>18 record.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. If you go to page 174 of</p> <p>21 Exhibit 43, the Oleckno textbook, there's a</p> <p>22 bullet point talking about statistical</p> <p>23 significance. I gave it to you as the last</p> <p>24 document we gave you.</p> <p>25 A. Sorry, it was not in front of</p>	<p>1 A. I do see where that's said.</p> <p>2 Q. And that's correct, right?</p> <p>3 A. That's correct.</p> <p>4 Q. All right. "Conversely, P</p> <p>5 greater than .05 indicates that the observed</p> <p>6 measure of association is probably due to</p> <p>7 chance alone and hence not statistically</p> <p>8 significant."</p> <p>9 Correct? Do you see that?</p> <p>10 A. I do see that, correct.</p> <p>11 Q. Okay. "Statistical</p> <p>12 significance does not indicate the strength</p> <p>13 of an association, nor does it reveal its</p> <p>14 practical significance. For a number of</p> <p>15 reasons, most epidemiologists prefer to use</p> <p>16 confidence intervals rather than</p> <p>17 significant -- significance testing. For one</p> <p>18 thing, these provide more information than</p> <p>19 significance testing."</p> <p>20 Do you see that?</p> <p>21 A. I do.</p> <p>22 Q. And do you agree with that?</p> <p>23 A. So there's a lot of statements</p> <p>24 there.</p> <p>25 Q. The last sentence, the last two</p>
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<p>1 me. I got it.</p> <p>2 Q. Okay. Go to page 174.</p> <p>3 A. This is a four-page summary of</p> <p>4 the textbook?</p> <p>5 Q. No, it's not a four-page</p> <p>6 summary of the textbook, Doctor. It is a</p> <p>7 page out of the textbook where he bullet</p> <p>8 points, and this is the point where he talks</p> <p>9 about statistical significance and</p> <p>10 significance testing.</p> <p>11 It says here, "Measures of</p> <p>12 association may be tested for statistical</p> <p>13 significance, i.e., if they significantly</p> <p>14 different {sic} from 1.0 for measures based</p> <p>15 on relative comparisons or significantly</p> <p>16 different from .0 for measures based on</p> <p>17 absolute comparisons. Statistical</p> <p>18 significance is rooted in hypothesis testing</p> <p>19 and is measured by the P value. Generally, P</p> <p>20 .05 indicates that an observed measure of</p> <p>21 association is unlikely to be due to chance</p> <p>22 alone based upon the assumption that there is</p> <p>23 no real association. Thus, it is considered</p> <p>24 statistically significant."</p> <p>25 You with me so far?</p>	<p>1 sentences I'm talking about.</p> <p>2 A. "For a number of reasons, most</p> <p>3 epidemiologists prefer to use confidence</p> <p>4 intervals rather than significance testing.</p> <p>5 For one thing, these provide more information</p> <p>6 than statistic -- significant testing."</p> <p>7 So it's an -- that's an</p> <p>8 important thing to consider, and I think we</p> <p>9 have to remember that statistical</p> <p>10 significance, a P value of less than .05,</p> <p>11 will give a confidence interval that does</p> <p>12 not -- that -- so if you have a statistically</p> <p>13 significant result, meaning that the P value</p> <p>14 is less than .05, then if you're looking at a</p> <p>15 measure of risk, then your confidence</p> <p>16 interval will not include 1.</p> <p>17 So they're not saying the</p> <p>18 same -- they're not saying different things.</p> <p>19 If your -- if your confidence interval does</p> <p>20 not include 1, then you're going to have a</p> <p>21 statistically significant result.</p> <p>22 The reason for looking at the</p> <p>23 confidence interval is because that gives you</p> <p>24 more information about the study. If the</p> <p>25 confidence interval is really, really tight,</p>

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<p style="text-align: right;">Page 410</p> <p>1 that means your measurement is really good or 2 your study sample is really, really big. 3 But you're not going to have a 4 statistically significant result if the 5 confidence interval crosses 1. It will be 6 statistically insignificant. 7 So dividing these things up is 8 not how this is meant to mean. What this 9 means is that the confidence interval just 10 gives you a little bit more information, but 11 they're not any different than each other. 12 It's the same thing. 13 (Merlo Exhibit 44 marked for 14 identification.) 15 QUESTIONS BY MR. TISI: 16 Q. All right. Doctor, I'm going 17 to show you what the American Statistical 18 Association says about this issue. I'm 19 attaching this as Exhibit Number 44. 20 I assume you've seen if you 21 read Dr. Ballman's testimony, because I think 22 it came out a couple of days before her 23 testimony. 24 A. Okay. 25 Q. I assume you've read this, sir?</p>	<p style="text-align: right;">Page 412</p> <p>1 QUESTIONS BY MR. TISI: 2 Q. So underneath -- on page 2, it 3 says, "Pervasive problem." And you 4 understand the American Statistical 5 Association published 42 articles in one 6 journal relating to this issue? 7 A. I have no idea what the 8 American association -- what was it called? 9 Q. Statistical association? 10 A. The American Statistical 11 Association, that's not something I follow, 12 so it's not -- I would have no idea whether 13 they published 42 articles or -- 14 Q. That's a good point. 15 What epidemiology journals do 16 you actually get? You mentioned the American 17 Epidemiology -- the American Epidemiology. 18 Any others that you get? 19 A. So I don't subscribe to 20 journals because we all -- we get them 21 through our Welch Library. We have access to 22 pretty much every journal available. And so 23 there are a number of epidemiologic journals 24 within the Welch Library that I have access 25 to.</p>
<p style="text-align: right;">Page 411</p> <p>1 A. I have looked this over, yes. 2 Q. It says -- under the section it 3 says, "Retire Statistical Significance." 4 That's the title of the -- of the article. 5 Retire? 6 A. I don't have that, actually. I 7 have "Sciences Rise Up Against Statistical 8 Significance." 9 Q. All right. Well, okay. I have 10 a different version. 11 MS. MILLER: Retire is nature. 12 THE WITNESS: And then I have 13 "Comment." So this is a comment. 14 QUESTIONS BY MR. TISI: 15 Q. Right. Correct. 16 A. Not a study. 17 Q. Right. I understand. 18 Your report is a comment, 19 right? 20 MR. LOCKE: Objection. 21 MS. MILLER: Objection. 22 THE WITNESS: My report is a 23 conglomeration of my opinions based on 24 the medical evidence. 25</p>	<p style="text-align: right;">Page 413</p> <p>1 Q. Which ones do you get? Which 2 one do you look at? 3 A. It would depend on the 4 situation. It would depend on the 5 investigation that I'm undertaking. 6 Q. Okay. Do you know who Sander 7 Greenland is? 8 A. I do not. 9 Q. Okay. So on page 2 of this 10 document, it says, "Let's be clear about what 11 must stop. We should never conclude that 12 there is no difference or no association just 13 because a P value is larger than the 14 threshold, such as P .05 or equivalent, 15 because confidence interval includes zero. 16 Neither should we conclude that two studies 17 conflict because one had a statistically 18 significant result and the other did not. 19 These errors waste research efforts and 20 misinform policy decisions." 21 Do you see that? 22 A. I do. 23 Q. Okay. I assume you disagree 24 with that given what you said before? 25 A. Again, I think it's going to</p>

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<p style="text-align: right;">Page 414</p> <p>1 depend, and the reason why I say it's going 2 to depend is because two studies may be 3 inherently different. One study may have a 4 very good study design and one study may have 5 a poor design. One study may adjust for bias 6 and confounding; one study may not. 7 And this is a very, very 8 generalized statement that can either be 9 agreed or disagreed with because of those. 10 Q. Okay. Doctor, I'm going to 11 show you a -- can you please take out the 12 article about misconceptions again, the 13 Rothman review which I -- you -- Exhibit 14 Number 28? 15 A. Exhibit 28? 16 Q. Uh-huh. 17 A. Okay. I have it. 18 Q. Misconception number 6, 1063. 19 Can you read it for the record, please? 20 A. Misconception -- which one? 21 Q. 6. 22 A. 6. Okay. 23 "Misconception 6. Significant 24 testing is useful and important for the 25 interpretation of data."</p>	<p style="text-align: right;">Page 416</p> <p>1 it depends, because it depends on the study 2 design. It depends on whether the 3 researchers decided to set up their study 4 well and properly control for bias, properly 5 adjust for potential for confounding, analyze 6 the results correctly. So all of those 7 factors have to -- have to come into balance. 8 And the interesting thing about 9 this paper is it's published in the Journal 10 of General Internal Medicine. And if he's an 11 epidemiologist and has these very important 12 misconceptions that he's trying to bring 13 forward in the epidemiology community, I'm 14 not sure why this wasn't published in an 15 epidemiology journal. 16 Q. Actually, in all fairness, 17 Doctor, I could have chosen dozens of 18 articles where Dr. Rothman makes the same, 19 including in his textbook. He has been very 20 adamant about this. So, I mean, you may not 21 understand it, but he has written about this 22 a lot. 23 So let me -- you made a 24 comment -- 25 MS. MILLER: We're going to</p>
<p style="text-align: right;">Page 415</p> <p>1 Q. And does it also say that -- on 2 the second column, second paragraph, 3 "Significant tests are a poor classification 4 scheme for study results. Strong effects may 5 be incorrectly interpreted as null findings 6 because the author" -- 7 A. I'm sorry to interrupt. Where 8 are you? 9 Q. Second paragraph. 10 A. Thank you. 11 Q. On the right-hand side. 12 A. I see it. 13 Q. "Significant tests are a poor 14 classification scheme for study results. 15 Strong effects may be incorrectly interpreted 16 as null findings because the authors 17 fallaciously interpret lack of statistical 18 significance or imply lack of effect or weak 19 effects may be incorrectly interpreted as 20 important because they are statistically 21 significant." 22 Do you see that? 23 A. I do see that. 24 Q. Do you agree with that? 25 A. So again, I'm just going to say</p>	<p style="text-align: right;">Page 417</p> <p>1 have to object to that speech and move 2 to strike that speech for the record. 3 QUESTIONS BY MR. TISI: 4 Q. You made a comment, and I 5 really have to push back on it. 6 Let's go to the conclusion -- 7 A. Are you asking me if I don't 8 understand it? 9 Q. Do you not -- do you not -- do 10 you understand it? 11 A. Understand what? 12 MS. MILLER: Objection. 13 QUESTIONS BY MR. TISI: 14 Q. I don't understand what your 15 question is. 16 MS. SHARKO: You don't have to 17 respond to the speeches, Doctor. 18 MS. MILLER: Yeah, just let it 19 go. 20 QUESTIONS BY MR. TISI: 21 Q. Doctor, if you go to the 22 conclusion in this thing, he says -- he makes 23 the following statement: "It is easy to 24 declare that the result is not statistically 25 significant, falsely implying that there is</p>

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<p style="text-align: right;">Page 418</p> <p>1 no indication of an association, rather than</p> <p>2 considering it the quantitative --</p> <p>3 quantitatively the range of associations that</p> <p>4 the data actually support."</p> <p>5 Do you see that?</p> <p>6 A. I do see that sentence.</p> <p>7 Q. Okay. And what he's talking</p> <p>8 about, the range of associations, is</p> <p>9 expressed by the confidence interval; is that</p> <p>10 correct?</p> <p>11 A. I don't know what he's</p> <p>12 referring to there.</p> <p>13 Q. Okay.</p> <p>14 A. But if he's talking about a</p> <p>15 nonstatistically significant result, then the</p> <p>16 confidence interval will include 1.</p> <p>17 (Merlo Exhibit 21 marked for</p> <p>18 identification.)</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. Okay. Doctor, I want to go</p> <p>21 back for a moment to the -- we were talking</p> <p>22 about the hospital-based studies and the</p> <p>23 heterogeneity, and we talked about Berge, and</p> <p>24 I want to talk about Penninkilampi for a</p> <p>25 moment.</p>	<p style="text-align: right;">Page 420</p> <p>1 A. Mucinous. Which ones?</p> <p>2 Mucinous, invasive mucinous, borderline?</p> <p>3 Q. Uh-huh.</p> <p>4 A. Yeah, with much -- a much lower</p> <p>5 number of studies that looked at that.</p> <p>6 Q. Would any bias or recall bias</p> <p>7 or confounding have -- what would that --</p> <p>8 what would explain that there would be a</p> <p>9 difference between serous tumors and</p> <p>10 nonserous tumors?</p> <p>11 Because I assume there would be</p> <p>12 no reason for a woman to recall exposure to</p> <p>13 one and not the other.</p> <p>14 MS. MILLER: Objection.</p> <p>15 Mischaracterizes this table, among</p> <p>16 other problems.</p> <p>17 THE WITNESS: I'm not sure what</p> <p>18 you're asking.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. Okay. Let's go on.</p> <p>21 On the qualitative data</p> <p>22 synthesis on page -- on the right-hand</p> <p>23 column, at the bottom of the second paragraph</p> <p>24 it says, "The only outcome" -- it talks about</p> <p>25 the three cohort studies.</p>
<p style="text-align: right;">Page 419</p> <p>1 I'll show the Penninkilampi</p> <p>2 study which you reviewed in your report.</p> <p>3 A. Thank you.</p> <p>4 Q. And that's exhibit number --</p> <p>5 Exhibit Number 21.</p> <p>6 You've seen this study before?</p> <p>7 A. Yes, I have.</p> <p>8 Q. First of all, I'm going like</p> <p>9 you to go to page 200 -- to page 44, please.</p> <p>10 It's the one with the table on it.</p> <p>11 A. 44, yes.</p> <p>12 Q. Now, it showed -- on the</p> <p>13 Table 1 it shows serous invasive and serous</p> <p>14 borderline tumors having a statistically</p> <p>15 significant elevated risk of 1.32 and 1.39</p> <p>16 respectively, correct?</p> <p>17 A. Serous invasive, serous</p> <p>18 borderline, 1.32, 1.39.</p> <p>19 Q. Okay. And this is a</p> <p>20 meta-analysis, true?</p> <p>21 A. This is a meta-analysis.</p> <p>22 Q. Okay. Now it does not show the</p> <p>23 same for mucinous, mucinous invasive, et</p> <p>24 cetera, right? It shows that they're not</p> <p>25 statistically significant?</p>	<p style="text-align: right;">Page 421</p> <p>1 "The only outcome reported in</p> <p>2 all three studies was any perineal talc use,</p> <p>3 hence the available data from prospective</p> <p>4 studies was limited."</p> <p>5 Do you see that?</p> <p>6 A. Can you point me to where</p> <p>7 you're reading?</p> <p>8 Q. (Indicating.)</p> <p>9 MS. MILLER: So it's the third</p> <p>10 to the last paragraph, the last</p> <p>11 sentence? Is that where you are?</p> <p>12 MR. TISI: It's the second</p> <p>13 paragraph on the right-hand side.</p> <p>14 THE WITNESS: The last sentence</p> <p>15 of the second paragraph?</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. The last sentence.</p> <p>18 "The only outcome reported in</p> <p>19 all three core studies was any perineal talc</p> <p>20 use." And that would be irrespective of</p> <p>21 duration, frequency, et cetera, right?</p> <p>22 A. That would refer to any</p> <p>23 perineal talc use if they're combined</p> <p>24 together.</p> <p>25 Q. Right.</p>

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<p style="text-align: right;">Page 422</p> <p>1 And there -- so he indicated</p> <p>2 that the available data from the prospective</p> <p>3 studies, meaning the cohort studies, was</p> <p>4 limited, true? It's what he says?</p> <p>5 A. In combining them it's limited,</p> <p>6 because the cohort studies may have not</p> <p>7 collected the same data about talc exposure.</p> <p>8 Q. Okay. It also says, "A</p> <p>9 subgroup analysis related to study population</p> <p>10 setting, i.e., hospitals or general</p> <p>11 population, was performed for any perineal</p> <p>12 use application."</p> <p>13 Do you see that?</p> <p>14 A. Yes, I do.</p> <p>15 Q. And the conclusion was, "There</p> <p>16 was no difference between the pooled results</p> <p>17 for hospital-based and population studies,</p> <p>18 OR, 1.22 versus 1.33 respectively."</p> <p>19 Do you see that?</p> <p>20 A. I do see that sentence, but I</p> <p>21 need see what that's referring to, what table</p> <p>22 and where that's coming from.</p> <p>23 Q. Well, have you reviewed this</p> <p>24 before?</p> <p>25 A. I have. I just haven't</p>	<p style="text-align: right;">Page 424</p> <p>1 interval of 1.01 to 1.55, heterogeneity, .33.</p> <p>2 Do you see that?</p> <p>3 A. Which line is that?</p> <p>4 Q. Under Types of Ovarian Cancer,</p> <p>5 Doctor. Right here.</p> <p>6 A. I see that.</p> <p>7 Q. Let's read what he says in</p> <p>8 conclusion. The conclusion that</p> <p>9 Dr. Penninkilampi reaches when he did his</p> <p>10 meta-analysis says -- and this is</p> <p>11 January 2018. "The results of this review</p> <p>12 indicate that perineal talc is associated</p> <p>13 with a 24 to 39 percent increased risk of</p> <p>14 ovarian cancer. While the case-control</p> <p>15 studies are prone to recall bias, especially</p> <p>16 with intense media attention following the</p> <p>17 commencement of a litigation in 2014, the</p> <p>18 confirmation of an association in cohort</p> <p>19 studies between perineal talc use and serous</p> <p>20 ovarian cancer is suggestive of a causal</p> <p>21 association."</p> <p>22 Do you see that?</p> <p>23 A. I do see that; however,</p> <p>24 Penninkilampi --</p> <p>25 Q. I didn't ask you a question. I</p>
<p style="text-align: right;">Page 423</p> <p>1 memorized it. There's a lot of papers out</p> <p>2 there.</p> <p>3 Q. Okay.</p> <p>4 A. And I don't know what that</p> <p>5 sentence is referring to.</p> <p>6 Q. Okay. Then it goes on to say,</p> <p>7 "There was heterogeneity in the analysis for</p> <p>8 non-perineal applications of talc. There was</p> <p>9 no heterogeneity for any other outcome</p> <p>10 measures in either the meta-analysis for all</p> <p>11 available studies or subgroup analysis."</p> <p>12 Do you see that?</p> <p>13 A. I do see that.</p> <p>14 Q. Okay. Do you agree with that?</p> <p>15 MS. MILLER: Objection.</p> <p>16 THE WITNESS: I would just need</p> <p>17 to see the table where it says that.</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. Well, haven't you seen it</p> <p>20 before?</p> <p>21 A. I have. I just haven't</p> <p>22 memorized it.</p> <p>23 Q. Okay. Well, if you go to</p> <p>24 Table 2, it talks about the type of cancers.</p> <p>25 Serous invasive has a 1.25 with a confidence</p>	<p style="text-align: right;">Page 425</p> <p>1 just asked --</p> <p>2 A. Well, I need to qualify this</p> <p>3 because Penninkilampi left out the -- left</p> <p>4 out Gates, and in Gates there was no</p> <p>5 association between serous.</p> <p>6 Q. I just asked you if you saw it.</p> <p>7 I'm going to ask you a follow-up question.</p> <p>8 Okay?</p> <p>9 Did you see it?</p> <p>10 Did I read it correctly?</p> <p>11 A. You read it correctly.</p> <p>12 Q. I assume you disagree with it.</p> <p>13 MS. MILLER: Objection.</p> <p>14 MR. LOCKE: Objection.</p> <p>15 THE WITNESS: I neither</p> <p>16 disagree -- I'm not disagreeing with</p> <p>17 it. It's just the -- what I do have</p> <p>18 an issue with is the methodology, and</p> <p>19 the methodology in this -- in this</p> <p>20 meta-analysis did not include the</p> <p>21 Gates study. And the Gates study is</p> <p>22 one that was a follow-up to Gertig</p> <p>23 using the same cohort, and that</p> <p>24 association was not in the Gates study</p> <p>25 when found in Gertig with bigger</p>

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<p>1 numbers.</p> <p>2 So I'm not agreeing or</p> <p>3 disagreeing with the statement. I'm</p> <p>4 disagreeing with the methodology that</p> <p>5 led to that statement.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. Now, you would agree with me</p> <p>8 that this article was peer-reviewed and</p> <p>9 published, right?</p> <p>10 A. I don't know. I don't know --</p> <p>11 I'm not -- I don't serve on the review</p> <p>12 committee for Epidemiology. I don't know</p> <p>13 what their practices are. I can only speak</p> <p>14 to the journals that I review for and whether</p> <p>15 or not those are peer-reviewed.</p> <p>16 Q. Doctor, isn't it true that</p> <p>17 every meta-analysis done in this case shows</p> <p>18 between a 25 and 40 percent increased --</p> <p>19 statistically significant increased risk of</p> <p>20 ovarian cancer?</p> <p>21 MS. MILLER: Objection.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Every published and even</p> <p>24 unpublished meta-analysis shows that risk?</p> <p>25 MR. LOCKE: Objection.</p>	<p>1 just wanted to make sure we were on</p> <p>2 the same page.</p> <p>3 MR. TISI: I don't know why you</p> <p>4 need to confirm that, but, okay, fine,</p> <p>5 I changed the question.</p> <p>6 THE WITNESS: So there are six</p> <p>7 meta-analyses that I reviewed, and</p> <p>8 again, it depends on what we're</p> <p>9 looking at here.</p> <p>10 There's a meta-analysis from</p> <p>11 1995 which -- done by Gross which may</p> <p>12 not have the same quality that</p> <p>13 meta-analyses done later because we</p> <p>14 learned how to do meta-analyses over</p> <p>15 time.</p> <p>16 But also have to remember that</p> <p>17 some of these meta-analyses broke</p> <p>18 things down by type of study, design,</p> <p>19 case-control versus cohort study, and</p> <p>20 even broke it down even further,</p> <p>21 breaking down the case-control studies</p> <p>22 into hospital-based versus</p> <p>23 population-based.</p> <p>24 And it's inappropriate to lump</p> <p>25 them all together, because they're</p>
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<p>1 MS. MILLER: Objection.</p> <p>2 THE WITNESS: We'd have to go</p> <p>3 through each specific one if you want</p> <p>4 me to --</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. Can you think of one that</p> <p>7 doesn't have a statistically significant</p> <p>8 increased risk?</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: Again, we'd have</p> <p>11 to go through each -- each one</p> <p>12 individually.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. I'm not asking -- I'm not</p> <p>15 asking you that.</p> <p>16 I'm asking, can you think of</p> <p>17 any meta-analysis that was published or not</p> <p>18 published that shows a nonstatistically</p> <p>19 significant result?</p> <p>20 A. Well --</p> <p>21 MS. MILLER: That's a different</p> <p>22 question.</p> <p>23 MR. TISI: I'm changing the</p> <p>24 question.</p> <p>25 MS. MILLER: Okay. Great. I</p>	<p>1 different study designs.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. But, Doctor, every one of these</p> <p>4 passed peer review, every single one, right?</p> <p>5 MS. MILLER: Objection.</p> <p>6 MR. LOCKE: Objection.</p> <p>7 THE WITNESS: And when you</p> <p>8 break things down further, for</p> <p>9 instance --</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. Well, my --</p> <p>12 A. -- in the Penninkilampi --</p> <p>13 Q. But that wasn't my question,</p> <p>14 Doctor, honestly.</p> <p>15 Every one of these studies</p> <p>16 passed peer review, did they not?</p> <p>17 A. Again, I'm not a -- I'm not a</p> <p>18 reviewer for these -- for these articles.</p> <p>19 Q. I didn't ask you whether you're</p> <p>20 a reviewer. I didn't ask you whether you</p> <p>21 reviewed them. I didn't ask whether you knew</p> <p>22 the process of review. I didn't ask whether</p> <p>23 you reviewed the reviewer comments. I didn't</p> <p>24 ask you anything.</p> <p>25 I asked you: They were all</p>

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<p>1 published in peer-reviewed journals, right?</p> <p>2 MR. LOCKE: Objection.</p> <p>3 THE WITNESS: I don't know.</p> <p>4</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. You don't know --</p> <p>7 A. I don't know if these are all</p> <p>8 peer-reviewed journals.</p> <p>9 Q. All right. Let's talk about</p> <p>10 dose response. That's the -- one of the Hill</p> <p>11 aspects, and you spent some time talking</p> <p>12 about that. And you discuss it on page 32 of</p> <p>13 your report.</p> <p>14 Do you see that, sir?</p> <p>15 A. I do see where I talk about</p> <p>16 dose response in my report.</p> <p>17 Q. And you claim on page 45 when</p> <p>18 you're criticizing plaintiffs' experts that</p> <p>19 plaintiffs' experts claim there was dose</p> <p>20 response when none exists, right?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. It's on page 45.</p> <p>24 A. I thought we were on page 32.</p> <p>25 Q. I said, you talk about your</p>	<p>1 literature out there and based on the</p> <p>2 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12,</p> <p>3 13, 14, 15, 16, 17 articles that may</p> <p>4 have -- sorry -- yeah, about that. I</p> <p>5 mean, I haven't tallied them up, but a</p> <p>6 bunch have attempted to look at dose</p> <p>7 response, and that dose response is</p> <p>8 just not there.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. First of all, is dose response</p> <p>11 required for Bradford Hill?</p> <p>12 MS. MILLER: Objection.</p> <p>13 THE WITNESS: Again, if we --</p> <p>14 if we go back to Bradford Hill,</p> <p>15 Bradford Hill has considerations, and</p> <p>16 those nine considerations oftentimes</p> <p>17 run into each other.</p> <p>18 Does one or another outweigh</p> <p>19 the other? They're usually used in</p> <p>20 combination.</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. Okay.</p> <p>23 A. Is one of them required and an</p> <p>24 absolute? They're considerations that in --</p> <p>25 used in combination can help provide</p>
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<p>1 opinions on lack of dose response, and you</p> <p>2 criticize plaintiffs' experts who claim there</p> <p>3 is dose response when none exist.</p> <p>4 A. So on page 32, they're not my</p> <p>5 opinions; that's what's found in the medical</p> <p>6 literature.</p> <p>7 Q. I got it. I hear you, Doctor.</p> <p>8 I'm saying your two parts of</p> <p>9 your discussion, you point out dose response</p> <p>10 on page 32, and that's your interpretation of</p> <p>11 the studies, and your criticisms of the</p> <p>12 plaintiffs' experts appear on page 45.</p> <p>13 MS. MILLER: Objection.</p> <p>14 THE WITNESS: On page 45, I</p> <p>15 talk about where there is no dose</p> <p>16 response, and that would be my</p> <p>17 opinion.</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. Right. And that plaintiffs are</p> <p>20 just flat out wrong, plaintiffs' experts?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: I didn't say --</p> <p>23 I'm not saying plain out, flat out</p> <p>24 wrong. What I'm saying is, my</p> <p>25 opinion, based on the medical</p>	<p>1 information on the causal pathway.</p> <p>2 Q. And it is often true with</p> <p>3 exposures as opposed to drugs that it is</p> <p>4 difficult to measure exposure, true?</p> <p>5 We talked about smoking. We</p> <p>6 talked about asbestos. We've talked about</p> <p>7 pollution. We've talked about benzene.</p> <p>8 We've talked about all different kinds of</p> <p>9 exposure.</p> <p>10 It is often difficult to know</p> <p>11 exactly how much a person gets, true?</p> <p>12 MS. MILLER: Objection.</p> <p>13 THE WITNESS: It depends. I</p> <p>14 mean, that's a very general statement.</p> <p>15 I think if we're -- if you have an</p> <p>16 accurate way of measuring something,</p> <p>17 then it's easier. If you don't,</p> <p>18 then --</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. Let's take cigarettes.</p> <p>21 A. -- it's more difficult.</p> <p>22 Q. Let's take cigarettes. We use</p> <p>23 pack years, right?</p> <p>24 A. Cigarettes? Pack years would</p> <p>25 be one estimate of the frequency and</p>

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<p style="text-align: right;">Page 434</p> <p>1 duration --</p> <p>2 Q. But you don't know how much --</p> <p>3 A. -- of exposure.</p> <p>4 Q. You don't know how much a</p> <p>5 person actually gets, how much they actually</p> <p>6 take into their lungs, whether they complete</p> <p>7 the whole cigarette, whether they go halfway</p> <p>8 and then put it out, whether they just puff</p> <p>9 on it. You don't really know how much they</p> <p>10 actually get, right?</p> <p>11 MS. MILLER: Objection.</p> <p>12 MR. LOCKE: Objection.</p> <p>13 THE WITNESS: Actually, I</p> <p>14 haven't reviewed the literature on</p> <p>15 this, and there may be studies out</p> <p>16 there that I'm just not aware of. And</p> <p>17 there may be studies that have looked</p> <p>18 at how much deposition goes into the</p> <p>19 lungs.</p> <p>20 We have studies looking at</p> <p>21 inhalational antibiotics, and we've</p> <p>22 studied actually how much gets into</p> <p>23 the lungs. I'd have to read</p> <p>24 literature on --</p> <p>25</p>	<p style="text-align: right;">Page 436</p> <p>1 Is it difficult to measure dose</p> <p>2 with exposures like this that are not drugs,</p> <p>3 for example?</p> <p>4 MS. MILLER: Objection.</p> <p>5 THE WITNESS: And I'll say it</p> <p>6 depends. If there is a reliable</p> <p>7 measure of -- if there's a reliable</p> <p>8 method of measuring something --</p> <p>9 because we're talking in generalities.</p> <p>10 If there's a reliable measure, then</p> <p>11 it's easier.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. What's the best way to measure</p> <p>14 talc exposure?</p> <p>15 MS. MILLER: Objection.</p> <p>16 THE WITNESS: Measuring talc</p> <p>17 exposure is -- would be very difficult</p> <p>18 to measure because of many, many</p> <p>19 factors.</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. Okay. And have you seen where</p> <p>22 articles attempted to figure out a way to do</p> <p>23 that?</p> <p>24 MS. MILLER: Objection.</p> <p>25 THE WITNESS: What kind of</p>
<p style="text-align: right;">Page 435</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. Well, those would be clinical</p> <p>3 trials, would they not be? Because you could</p> <p>4 measure that because you're in a controlled</p> <p>5 environment, right?</p> <p>6 A. I'm not sure what you're</p> <p>7 asking.</p> <p>8 Q. What I'm saying is, when you're</p> <p>9 doing an occupational exposure like this, it</p> <p>10 is oftentimes difficult to measure dose --</p> <p>11 MS. MILLER: Objection.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. -- as a general matter?</p> <p>14 MS. MILLER: Objection.</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. I mean, I think it's a point</p> <p>17 Dr. Diette made. We sat with Dr. Diette last</p> <p>18 week. He said it's very difficult to measure</p> <p>19 dose.</p> <p>20 MS. MILLER: Objection.</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: Can you ask me</p> <p>23 that question again?</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. Yes.</p>	<p style="text-align: right;">Page 437</p> <p>1 articles are you referring to?</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. The epidemiology studies, never</p> <p>4 versus ever, breaking it down by weeks, days,</p> <p>5 months, years, et cetera.</p> <p>6 Have you seen those kinds of --</p> <p>7 those kinds of attempts?</p> <p>8 MR. LOCKE: Objection.</p> <p>9 THE WITNESS: So there are --</p> <p>10 there have been articles that have</p> <p>11 attempted to look at frequency of</p> <p>12 duration and those sorts of things,</p> <p>13 but I think we need to step back a</p> <p>14 little bit because what I'm talking</p> <p>15 about is it's -- it's not a</p> <p>16 medication. There are no pharmacy</p> <p>17 records. There's no dosing. I have</p> <p>18 no idea -- and I don't think anyone</p> <p>19 can tell what -- how much comes out if</p> <p>20 someone's pouring talc on a sanitary</p> <p>21 napkin or underwear or placing talc in</p> <p>22 the perineal area. There's no way to</p> <p>23 know. And there's no article in the</p> <p>24 medical literature that looks at that</p> <p>25 as a measure of exposure.</p>

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<p style="text-align: right;">Page 438</p> <p>1 And that's actually more</p> <p>2 important than frequency and duration</p> <p>3 because we have no idea what even goes</p> <p>4 into that frequency and duration.</p> <p>5 (Merlo Exhibit 30 marked for</p> <p>6 identification.)</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. I'm going to show you what I</p> <p>9 have marked as Exhibit Number 30, which is an</p> <p>10 meta-analysis by Taher. It's not been</p> <p>11 published yet, but it is the draft that we</p> <p>12 have that's been commissioned by Health</p> <p>13 Canada.</p> <p>14 You've seen this before, right?</p> <p>15 A. I've seen Taher. I'm not aware</p> <p>16 that it's commissioned by Health Canada.</p> <p>17 Q. I'll represent to you that it</p> <p>18 is.</p> <p>19 When did you see this study for</p> <p>20 the first time?</p> <p>21 A. I don't recall. Sometime after</p> <p>22 December.</p> <p>23 Q. So if you look at -- if you</p> <p>24 look at the conclusion on the one that says</p> <p>25 page 49 on the bottom, P2.00344.9, it says,</p>	<p style="text-align: right;">Page 440</p> <p>1 off the record for this.</p> <p>2 MR. TISI: Given the way your</p> <p>3 experts have filed things with Health</p> <p>4 Canada, with Dr. Nicholson, not</p> <p>5 identifying who she was when she was</p> <p>6 writing for the Cosmetic Association</p> <p>7 of Canada, I don't think you get to</p> <p>8 talk.</p> <p>9 MS. SHARKO: I think your</p> <p>10 comments are totally off base. You</p> <p>11 asked me why we laughed.</p> <p>12 MR. TISI: It's not even</p> <p>13 appropriate to laugh. Even if you</p> <p>14 thought it was funny, it's not</p> <p>15 appropriate.</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. Doctor --</p> <p>18 MS. SHARKO: Well, then don't</p> <p>19 make the obnoxious comments.</p> <p>20 MR. TISI: You don't think</p> <p>21 laughing is obnoxious?</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. On page 26, the summary of</p> <p>24 evidence on biologic gradient exposure</p> <p>25 response.</p>
<p style="text-align: right;">Page 439</p> <p>1 source of funding. "This work was supported</p> <p>2 by Health Canada."</p> <p>3 Do you see that?</p> <p>4 A. I do. "This work was supported</p> <p>5 by Health Canada."</p> <p>6 Q. Do you think Health Canada is</p> <p>7 involved with this litigation?</p> <p>8 MR. LOCKE: Objection.</p> <p>9 THE WITNESS: Again, I told you</p> <p>10 I don't know anything about Health</p> <p>11 Canada.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. Do you think that this --</p> <p>14 MR. TISI: You want to talk</p> <p>15 about inappropriate, that was totally</p> <p>16 inappropriate, that laughter.</p> <p>17 MS. SHARKO: Given this --</p> <p>18 given the way your experts are having</p> <p>19 this big ex parte communication with</p> <p>20 Health Canada, I don't think so,</p> <p>21 Mr. Tisi.</p> <p>22 MR. TISI: Given the way --</p> <p>23 given the way -- given the way -- wait</p> <p>24 a second.</p> <p>25 MS. PARFITT: Chris, let's go</p>	<p style="text-align: right;">Page 441</p> <p>1 A. 26?</p> <p>2 Q. There's a chart.</p> <p>3 A. I see it.</p> <p>4 Q. Okay? It discusses -- it</p> <p>5 summarizes the evidence on biologic gradient.</p> <p>6 It says, "About half of the epidemiologic</p> <p>7 studies assessed only one level of talc</p> <p>8 exposure, ever versus never usage."</p> <p>9 Is that correct?</p> <p>10 MR. LOCKE: Objection.</p> <p>11 MS. MILLER: Objection.</p> <p>12 Are you asking --</p> <p>13 MR. TISI: I'm asking what I'm</p> <p>14 asking.</p> <p>15 MS. MILLER: -- whether you</p> <p>16 read it correctly?</p> <p>17 MR. TISI: No. I'm asking is</p> <p>18 that correct.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. "About half of the epidemiology</p> <p>21 studies assessed only one level of talc</p> <p>22 usage, ever versus never."</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: You know, I would</p> <p>25 have -- I don't have these things</p>

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<p style="text-align: right;">Page 442</p> <p>1 memorized. I'm going to have to go 2 back to each individual article and 3 look to see if it's about half. 4 That's not something that I have 5 memorized. 6 I know that I did look into the 7 different exposure categories or the 8 different levels of exposure in each 9 study, but I didn't lump those into 10 that kind of broad category. 11 QUESTIONS BY MR. TISI: 12 Q. The next one says, "Of the 12 13 studies reporting a positive association, six 14 studies found a significant exposure response 15 trend, particularly with medium and high 16 frequency usage groups. Regarding duration 17 of use, exposure to talc, several studies 18 reported the greatest risk in 20-plus years 19 of exposure group followed by 10 to 20 years 20 group, then less than 10 years group." 21 Do you see that? 22 A. I do see that statement. 23 Q. Now, Bradford Hill doesn't 24 require proof of dose response. It just says 25 if there is evidence of it, that's supportive</p>	<p style="text-align: right;">Page 444</p> <p>1 a biologic gradient, then we should 2 look for it. 3 QUESTIONS BY MR. TISI: 4 Q. Right. 5 And should look for evidence of 6 it? 7 A. Look for such evidence. 8 Q. Right. 9 And it goes -- down at the 10 bottom it says, "Often the difficulty is to 11 secure some satisfactory quantitative measure 12 of environment which will permit us to 13 explore dose response, but we should 14 invariably seek it." 15 Do you agree with that? 16 MS. MILLER: Objection. 17 THE WITNESS: Can you ask me 18 that again? I'm sorry. 19 QUESTIONS BY MR. TISI: 20 Q. Yes. 21 It says, "Often the difficulty 22 in to secure some satisfactory quantitative 23 measure of environment which would permit us 24 to explore this dose response, but we should 25 invariably seek it."</p>
<p style="text-align: right;">Page 443</p> <p>1 of causation, correct? 2 MR. LOCKE: Objection. 3 THE WITNESS: Well, I'm going 4 to have to -- 5 QUESTIONS BY MR. TISI: 6 Q. Let's get it. 7 A. -- refer back to Bradford Hill 8 and see what he says. 9 Q. Let's see what he says. 10 Exhibit Number 14. 11 It's on page 10. 12 A. Okay. 13 Q. It says, "If" -- "Fifthly, if 14 the association is one which can reveal a 15 biologic gradient or a dose-response curve, 16 then we should look most carefully for such 17 evidence." 18 Do you see that? 19 A. I do see that. 20 Q. It doesn't say statistically 21 significant evidence, it doesn't say studies 22 which demonstrate it, does it? 23 MR. LOCKE: Objection. 24 THE WITNESS: It says that if 25 the association is one that can reveal</p>	<p style="text-align: right;">Page 445</p> <p>1 A. That's correct. 2 Q. All right. And so in trying to 3 seek the evidence, these authors, not 4 involved in litigation, found that there was 5 at least evidence of a dose response, 6 correct? 7 MR. LOCKE: Objection. 8 THE WITNESS: I'm going to have 9 to turn back to that page again and 10 look at it because I don't know the 11 exact words. 12 What page is that on again? 13 26? 14 QUESTIONS BY MR. TISI: 15 Q. Yes. And I'll read it again, 16 Doctor. 17 "Of the 12 studies reporting a 18 positive association, six studies found 19 significant exposure response trends, 20 particularly with medium and high frequency 21 usage groups. Regarding duration of use, 22 exposure to talc, several studies reported 23 the greatest risk in the 20-plus years of 24 exposure group, followed by 10 to 20, then 25 less than 10 years."</p>



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<p style="text-align: right;">Page 446</p> <p>1 A. So...</p> <p>2 MR. LOCKE: Is there a</p> <p>3 question?</p> <p>4 MR. TISI: Yes. That's the</p> <p>5 section I was referring to.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. Isn't that what they found?</p> <p>8 A. That's what they say.</p> <p>9 (Merlo Exhibit 46 marked for</p> <p>10 identification.)</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Okay. Let me show you Exhibit</p> <p>13 Number 46, which is a compilation exhibit</p> <p>14 that I pulled together, and I tabbed it for</p> <p>15 you with the actual articles. And you can</p> <p>16 check my quotations from it.</p> <p>17 MS. MILLER: I'm going to</p> <p>18 object to this exhibit, of course.</p> <p>19 MR. TISI: Of course you are.</p> <p>20 MS. MILLER: Because you once</p> <p>21 again just pulled random sentences out</p> <p>22 of studies --</p> <p>23 MR. TISI: Okay.</p> <p>24 MS. MILLER: -- that do not</p> <p>25 account for the entire body of</p>	<p style="text-align: right;">Page 448</p> <p>1 genital talc use and ovarian cancer, which</p> <p>2 appears to be limited to serous carcinoma</p> <p>3 with suggestion of dose response."</p> <p>4 Is that --</p> <p>5 MS. MILLER: So you've got the</p> <p>6 ellipses leaving out the "which</p> <p>7 appears to be limited to serous</p> <p>8 carcinoma"?</p> <p>9 MR. TISI: I'm reading it from</p> <p>10 the study, Doctor.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Am I reading that correctly, if</p> <p>13 you look at it?</p> <p>14 MR. LOCKE: Objection. Asked</p> <p>15 and answered.</p> <p>16 THE WITNESS: You're reading</p> <p>17 the abstract.</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. Yes. Is that correct.</p> <p>20 I'm just asking you, Doctor,</p> <p>21 whether it says that.</p> <p>22 A. And I said that's what it says</p> <p>23 in the abstract, and I'm looking for where</p> <p>24 that is actually represented in the -- in the</p> <p>25 article.</p>
<p style="text-align: right;">Page 447</p> <p>1 statements within the studies.</p> <p>2 MR. TISI: Okay.</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. Now, Doctor, if you look, I</p> <p>5 have the Berge studies we talked about</p> <p>6 before. And you saw the statement, "The</p> <p>7 meta-analysis results in a weak but</p> <p>8 statistically significant association between</p> <p>9 genital use of talc and ovarian cancer which</p> <p>10 appears to be limited to serous with a</p> <p>11 suggestion of dose response."</p> <p>12 Is that correct?</p> <p>13 MR. LOCKE: Objection.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Is that there in? Can you</p> <p>16 confirm that that's there?</p> <p>17 MS. MILLER: You just said --</p> <p>18 MR. LOCKE: Objection.</p> <p>19 MS. MILLER: That was so fast.</p> <p>20 THE WITNESS: Confirm where</p> <p>21 what is where?</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Okay. Number one says, "The</p> <p>24 meta-analysis resulted in a weak but</p> <p>25 statistically significant association between</p>	<p style="text-align: right;">Page 449</p> <p>1 Q. And in number 2 it says -- on</p> <p>2 the Schildkraut study it has a quote, and</p> <p>3 let's turn to the Schildkraut study. And</p> <p>4 that's number 2. And if you go to page --</p> <p>5 A. But if I could just say,</p> <p>6 because I did find this Table 3 right now,</p> <p>7 looks at duration and frequency.</p> <p>8 Q. Uh-huh.</p> <p>9 A. And the number of risk</p> <p>10 estimates are 12 and the relative risk 1.16,</p> <p>11 with a 95 percent confidence interval, 1.07</p> <p>12 to 1.26. This is just dichotomized duration,</p> <p>13 ten years. This isn't -- that's not a dose</p> <p>14 response. That's yes or no.</p> <p>15 Q. Okay.</p> <p>16 A. Less than ten years or more</p> <p>17 than ten years.</p> <p>18 Q. Okay. Now --</p> <p>19 A. Frequency, one time a week.</p> <p>20 That's not -- that's not a frequency.</p> <p>21 That's -- that's a yes/no, and that's a</p> <p>22 dichotomized -- so that's not a dose</p> <p>23 response.</p> <p>24 Q. Okay. Doctor, in the</p> <p>25 Schildkraut study on number 2, does the</p>

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<p style="text-align: right;">Page 450</p> <p>1 Schildkraut author say on page -- and then if 2 you look at number 2, which is the second 3 article attached on page 1416, the second -- 4 left-hand side, second to last paragraph, 5 second sentence, it says, "The dose response 6 observed for duration of genital powder use 7 provides further evidence of the relationship 8 between genital powder and overall EOC risk." 9 Do you see that? 10 MR. LOCKE: Objection. 11 QUESTIONS BY MR. TISI: 12 Q. I highlighted it for you to 13 make it easy. 14 A. That's what is said in the -- 15 in the paper; however, when you look at 16 Table 2, duration of use, again, it's 17 dichotomized into less than 20 years or 18 greater than 20 years. So there's no full -- 19 never use and genital use. 20 And then it's looked at 21 lifetime body powder applications. Again, 22 dichotomized in above median, 3,600, or 23 below -- or above 3,600. 24 That's not a dose response. A 25 dose response is multiple categories. This</p>	<p style="text-align: right;">Page 452</p> <p>1 dose response? 2 Do you see that? 3 MR. LOCKE: Objection. 4 QUESTIONS BY MR. TISI: 5 Q. Does it not say that, Doctor? 6 Do you see where I'm at, 7 Doctor? 8 A. I do. 9 Q. Okay. Does in not say that? 10 A. It says, "An odds ratio of 1.49 11 was associated with more" -- and I'm sorry, I 12 had to skip a couple pages -- "than 20 talc 13 years, greater than 7,200 applications" -- 14 Q. And -- 15 A. -- "in a dose response." 16 Q. And if you go to page -- 17 A. However, I would like to just 18 look at -- 19 Q. Your lawyer can ask you 20 questions. I asked whether that's in the 21 published article. 22 The next is on page 345, in 23 summary. 24 Do you see that? 25 It says, "Overall, there's an</p>
<p style="text-align: right;">Page 451</p> <p>1 is a dichotomy. This is a yes or no. Is it 2 more or less. That's not a dose response. 3 Q. Okay. Doctor, that's what the 4 authors say that's in the published 5 peer-reviewed literature, correct? 6 MR. LOCKE: Objection. 7 MS. MILLER: Objection. 8 THE WITNESS: I said that 9 that's what it said, but that's not 10 what dose -- 11 QUESTIONS BY MR. TISI: 12 Q. Okay. So why are you going any 13 further than what I asked you? 14 MR. LOCKE: Objection. 15 THE WITNESS: Because that's 16 not what a dose response represents. 17 QUESTIONS BY MR. TISI: 18 Q. All right. Let's go to the 19 next one. Let's go to the Cramer study, 20 which is number 3 and 4. There's two 21 statements here. One is on page 335, and 22 I've highlighted it. 23 Does it say an odds ratio of 24 1.49 was associated with more than 20 talc 25 years, greater than 7,200 applications, in a</p>	<p style="text-align: right;">Page 453</p> <p>1 association between genital talc use and EOC 2 in a significant trend with increasing talc 3 years' use." 4 MR. LOCKE: Is there a 5 question? 6 MR. TISI: Yes. I said, is 7 that correct? 8 MS. MILLER: Is what correct? 9 MR. LOCKE: Objection. 10 QUESTIONS BY MR. TISI: 11 Q. I said do you see it. On 12 page 345, number 1 in the Cramer study, the 13 authors report in the peer-review literature: 14 "Overall, there is an association between 15 genital talc use and epithelial ovarian 16 cancer in a significant trend with increasing 17 talc years' of use." 18 Did I read that right? 19 A. I see that written there. 20 Q. And does it appear in the 21 peer-reviewed literature? 22 MS. MILLER: Objection. 23 THE WITNESS: Again, this is -- 24 it's in the literature. 25</p>

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<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. Okay.</p> <p>3 A. I can't comment on whether it</p> <p>4 was peer-reviewed or not.</p> <p>5 Q. Okay. And the next study,</p> <p>6 which is the Terry study -- you've seen that</p> <p>7 study before as well, Doctor? That's</p> <p>8 number 5?</p> <p>9 A. I have.</p> <p>10 Q. Okay. All right. Do you see</p> <p>11 where -- the statement where it says -- I</p> <p>12 highlighted it for you. "The association</p> <p>13 between genital powder exposure and ovarian</p> <p>14 cancer may not be linear, and a modest</p> <p>15 exposure may be sufficient to increase the</p> <p>16 cancer risk."</p> <p>17 Do you see that?</p> <p>18 A. I do see that.</p> <p>19 Q. Okay. Next one is Wu. That's</p> <p>20 the one where I think you agree there was</p> <p>21 evidence of dose response, correct?</p> <p>22 A. Well, the statement in the</p> <p>23 Terry where it just says, "Alternatively, the</p> <p>24 associate" -- that's not saying that there's</p> <p>25 a dose response. That's just stating</p>	<p>1 "However, only about half the studies</p> <p>2 examined exposure response relationships, and</p> <p>3 the evidence for this is less consistent.</p> <p>4 Our study adds to the small group of studies</p> <p>5 that have investigated a combination of</p> <p>6 frequency and duration of use of ovarian</p> <p>7 cancer -- on ovarian cancer."</p> <p>8 A. So I think -- I think in my</p> <p>9 report I actually said that Wu, there's a</p> <p>10 suggestion of a dose response, as well as</p> <p>11 Cramer 2016, there is a suggestion of dose</p> <p>12 response.</p> <p>13 But all the cutoffs were not</p> <p>14 statistically significant, so, you know --</p> <p>15 Q. But, of course -- but, of</p> <p>16 course, we just agreed that Bradford Hill</p> <p>17 doesn't require a statistically significant</p> <p>18 result on dose response. Just says it's good</p> <p>19 if you have evidence of it.</p> <p>20 MS. MILLER: Objection.</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: I didn't agree to</p> <p>23 that. I think that I have to take</p> <p>24 what this table tells me, and if there</p> <p>25 is evidence of a dose response based</p>
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<p>1 something.</p> <p>2 Q. Okay.</p> <p>3 A. It says nothing about dose</p> <p>4 response.</p> <p>5 Q. Next one is Wu, number 5. I'm</p> <p>6 sorry, number 6.</p> <p>7 A. Number 6.</p> <p>8 Q. Okay. In the abstract, does it</p> <p>9 not say, "Risk of ovarian cancer increased</p> <p>10 significantly with increasing frequency and</p> <p>11 duration of talc use"?</p> <p>12 A. So in Wu -- just trying to flip</p> <p>13 through these.</p> <p>14 Where'd you read that?</p> <p>15 Q. In the abstract. It's</p> <p>16 highlighted for you, Doctor.</p> <p>17 A. There's a lot going on here</p> <p>18 really quickly, so I'm just trying my hardest</p> <p>19 to read everything.</p> <p>20 So in the abstract it says,</p> <p>21 "Risk of ovarian cancer increased</p> <p>22 significantly with increasing frequency and</p> <p>23 duration of talc use."</p> <p>24 Q. And does it also say -- and I</p> <p>25 highlighted it for you as well in the back --</p>	<p>1 on what the numbers look like and is</p> <p>2 there a consistent increase in risk</p> <p>3 with increasing duration and</p> <p>4 frequency, and those numbers are</p> <p>5 statistically significant, then that</p> <p>6 would suggest a dose response.</p> <p>7 However, if we look at the risk</p> <p>8 estimates in Wu here, looking at</p> <p>9 Table 2, looking at total number of</p> <p>10 times, yeah, there is a -- there is a</p> <p>11 suggestion that there is an increase</p> <p>12 in risk estimate with increasing</p> <p>13 number of talc uses, but those numbers</p> <p>14 are not statistically significant. So</p> <p>15 they could all be the same or be</p> <p>16 solely due to chance.</p> <p>17 MR. TISI: I'm going to take --</p> <p>18 THE WITNESS: So it depends.</p> <p>19 MR. TISI: Okay. I want to</p> <p>20 take a break.</p> <p>21 VIDEOGRAPHER: The time is</p> <p>22 5:22 p.m. We're going off the record.</p> <p>23 (Off the record at 5:22 p.m.)</p> <p>24 VIDEOGRAPHER: The time is</p> <p>25 5:36 p.m. We're back on the record.</p>

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<p style="text-align: right;">Page 458</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. Doctor, can you go back to</p> <p>3 Exhibit 32, which was the -- Chapter 2 out of</p> <p>4 the Rothman textbook.</p> <p>5 A. I have it here.</p> <p>6 Q. If you can go to the section on</p> <p>7 biologic gradient.</p> <p>8 MS. MILLER: Can you point us</p> <p>9 to a page?</p> <p>10 MR. TISI: Yeah. It's 28.</p> <p>11 THE WITNESS: 28.</p> <p>12 MS. MILLER: Like where it says</p> <p>13 out of 30?</p> <p>14 MR. TISI: You know, I don't</p> <p>15 have my copy right there. I'm just</p> <p>16 using the book.</p> <p>17 MS. MILLER: Sorry. There's</p> <p>18 like different page numbers.</p> <p>19 MR. TISI: Yeah, if you just</p> <p>20 give me -- it's the one that -- maybe</p> <p>21 I will look at yours. Thank you.</p> <p>22 MS. MILLER: Sure.</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. It's page -- it's page 27 out</p> <p>25 of 30.</p>	<p style="text-align: right;">Page 460</p> <p>1 curve. But that -- but that's just</p> <p>2 describing the curve.</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. The last sentence of this says,</p> <p>5 "The issues imply that a -- existence of a</p> <p>6 monotonic association is neither necessary</p> <p>7 nor sufficient for causal relation."</p> <p>8 Is that true or not true?</p> <p>9 A. And I would just have to look</p> <p>10 up to see what monotonic is being defined as.</p> <p>11 Q. So you don't have any</p> <p>12 understanding what the word "monotonic"</p> <p>13 means?</p> <p>14 MS. MILLER: Objection.</p> <p>15 THE WITNESS: Well, I have an</p> <p>16 understanding, but I need to know what</p> <p>17 monotonic is being referred to as</p> <p>18 here.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. Well, what do you -- how do you</p> <p>21 define monotonic?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: Usually monotonic</p> <p>24 means that there is an increasing risk</p> <p>25 with increasing dose, or a decreasing</p>
<p style="text-align: right;">Page 459</p> <p>1 A. I see it.</p> <p>2 Q. Okay. Do you agree that not</p> <p>3 all bio -- all dose-response relationships</p> <p>4 are linear?</p> <p>5 MS. MILLER: Objection.</p> <p>6 THE WITNESS: There may be</p> <p>7 dose-response relationships that could</p> <p>8 be linear, there may be dose-response</p> <p>9 relationships that may be exponential,</p> <p>10 but in general, a dose response has an</p> <p>11 increasing risk with increasing dose.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. Right.</p> <p>14 But they could be like U-shaped</p> <p>15 curves; they can be J-shaped curves; they</p> <p>16 could be monotonic associations; they could</p> <p>17 be all kinds of associations, right?</p> <p>18 MS. MILLER: Objection.</p> <p>19 THE WITNESS: So if we're</p> <p>20 talking about curves, a curve can look</p> <p>21 like anything. It can be a straight</p> <p>22 line. It can be something that -- J</p> <p>23 goes like a J shape, like you're</p> <p>24 saying. There could be a convex</p> <p>25 curve. There could be a concave</p>	<p style="text-align: right;">Page 461</p> <p>1 risk with decreasing dose.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Okay. Let's just use your</p> <p>4 definition.</p> <p>5 Is the monotonic association</p> <p>6 either necessary or sufficient for causal</p> <p>7 relationship?</p> <p>8 A. Can you ask that again?</p> <p>9 Q. Yeah.</p> <p>10 I'm referring to the sentence</p> <p>11 that -- and Dr. Rothman says, "These issues</p> <p>12 imply that the existence of a monotonic</p> <p>13 association is neither necessary nor</p> <p>14 sufficient for causal relation."</p> <p>15 Is that true or not true using</p> <p>16 your definition of monotonic?</p> <p>17 A. Well, if we go back to the</p> <p>18 original Bradford Hill considerations,</p> <p>19 biologic gradient is only one of the</p> <p>20 considerations. And if we're talking about a</p> <p>21 causal relationship, we need to consider the</p> <p>22 other considerations as well.</p> <p>23 Q. But, Doctor, that's not my</p> <p>24 question. Okay?</p> <p>25 So my question is -- I'm</p>

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<p style="text-align: right;">Page 462</p> <p>1 focused now on biologic gradient or dose 2 response. 3 Would you agree with 4 Dr. Rothman that a monotonic association, 5 meaning increasing dose with increasing 6 duration -- with increasing risk, is neither 7 necessary nor sufficient for causal relation? 8 MS. MILLER: Objection. 9 THE WITNESS: And again, I'm 10 going to have to go back to what I 11 just said because I'm not sure what 12 Dr. Rothman is referring to here. 13 Is it just specifically for 14 biologic gradient -- 15 QUESTIONS BY MR. TISI: 16 Q. Yeah. 17 A. -- or is it -- well -- 18 Q. Let's assume that's what he's 19 saying, because I want to know if, on its 20 own, a -- on its own, is it necessary to have 21 a increasing risk with increasing dose -- 22 MS. MILLER: Objection. 23 QUESTIONS BY MR. TISI: 24 Q. -- to show causation? 25 MS. MILLER: Objection.</p>	<p style="text-align: right;">Page 464</p> <p>1 Remember that? 2 MR. LOCKE: Objection. 3 THE WITNESS: We would have to 4 refer back to what -- what I said. 5 QUESTIONS BY MR. TISI: 6 Q. Okay. 7 A. I don't recall specifically my 8 language. 9 Q. Is it necessary to have a 10 dose-response relationship in order to show 11 causation? Is that a required element? 12 A. I think what I said earlier is 13 that of the nine Bradford Hill 14 considerations, none of them are required. 15 Q. Okay. 16 A. They're helpful in making an -- 17 in making -- in putting together an 18 evaluation looking at causality. 19 Q. Is Dr. Rothman's statement here 20 wrong? 21 MS. MILLER: Objection. 22 QUESTIONS BY MR. TISI: 23 Q. Is the existence of a monotonic 24 association -- he says, "The existence of a 25 monotonic association is neither necessary</p>
<p style="text-align: right;">Page 463</p> <p>1 THE WITNESS: Again, I will go 2 back to the Bradford Hill 3 considerations, and that of the nine 4 considerations, none of them or all of 5 them could support causation. 6 QUESTIONS BY MR. TISI: 7 Q. Okay. 8 A. I'm not going to say none of 9 them, but all of them could support 10 causation. 11 Does one factor -- does one 12 factor weigh in more than another factor? 13 Not necessarily. 14 And this sentence can't be 15 taken out of context in the -- from the 16 Bradford Hill considerations. 17 Q. I hear you, Doctor, but I'm 18 going to ask you to listen to my question. 19 Is it necessary to have a dose 20 response to find causation? 21 You said before that it was 22 necessary to have a consistent association, I 23 think a clear association -- that was your 24 testimony before -- to even get to Bradford 25 Hill.</p>	<p style="text-align: right;">Page 465</p> <p>1 nor sufficient for causal relations." 2 Is that wrong? 3 MS. MILLER: Objection. 4 THE WITNESS: I'm going to say 5 it depends. If you have nine other -- 6 or eight other factors that suggest 7 causation and there's -- and a 8 biologic gradient doesn't exist 9 because you haven't tested for it or 10 it's just isn't showing that, you have 11 to consider the other factors. 12 If biologic gradient is the 13 only thing, and we're not seeing 14 strength of association and 15 consistency, then it becomes difficult 16 to rely on that -- just the biologic 17 gradient. So I'm just going to say it 18 depends. 19 QUESTIONS BY MR. TISI: 20 Q. Okay. So if you go to the 21 Penninkilampi study back -- I forget which 22 exhibit it was. But if you can pull that out 23 if you can find it, sir. 24 A. Sure. 25 MR. TISI: Do you know what</p>

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<p style="text-align: right;">Page 466</p> <p>1 exhibit it was?</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. 21, please.</p> <p>4 A. 21. Got it.</p> <p>5 Q. You were critical of that study</p> <p>6 because Penninkilampi included Gertig but not</p> <p>7 Gates.</p> <p>8 Do you recall that?</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: I did make</p> <p>11 reference that Gertig was included in</p> <p>12 this meta-analysis and Gates was not,</p> <p>13 which is a more recent publication</p> <p>14 with greater numbers.</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. Which Gates did you mean?</p> <p>17 Which Gates study did you mean should have</p> <p>18 been included that wasn't?</p> <p>19 A. I'll just need to look up the</p> <p>20 specific one in my report. Gates 2010.</p> <p>21 Q. Okay. What was the talc</p> <p>22 exposure metric in Gates 2010?</p> <p>23 A. If I could see the article, I</p> <p>24 could...</p> <p>25 Q. Is it in your report?</p>	<p style="text-align: right;">Page 468</p> <p>1 asked that question.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Could that have been --</p> <p>4 MR. TISI: Counsel, I'm not</p> <p>5 even done, okay?</p> <p>6 MS. MILLER: It sounded like a</p> <p>7 question.</p> <p>8 MR. TISI: I'm not done.</p> <p>9 MS. MILLER: Apologies.</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. In the Gates -- in the Gates</p> <p>12 study, do you know that talc use metric was</p> <p>13 great or equal to one week versus less --</p> <p>14 versus less than one time a week?</p> <p>15 MS. MILLER: Objection.</p> <p>16 THE WITNESS: I'd love to look</p> <p>17 at it.</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. I'm happy to show it. I'm</p> <p>20 happy to show it to you. It's my copy, so</p> <p>21 you can't have it. But it's in Table 4, and</p> <p>22 this is Gates 2010.</p> <p>23 A. So Table 4 says, talc use,</p> <p>24 greater than once a week versus less than</p> <p>25 once a week.</p>
<p style="text-align: right;">Page 467</p> <p>1 A. I could point to it.</p> <p>2 Q. Is it in your report?</p> <p>3 A. No, but I know that it was --</p> <p>4 but I would have to see the article because I</p> <p>5 don't specifically remember what the</p> <p>6 actual -- I don't want to be mistaken right</p> <p>7 now.</p> <p>8 Q. Well, Penninkilampi used an</p> <p>9 ever use of talc, correct, as its metric?</p> <p>10 A. I mean, Table 1 in</p> <p>11 Penninkilampi summarizes the different</p> <p>12 outcomes in the methods of talc use.</p> <p>13 Q. Right.</p> <p>14 A. There's any perineal, there's</p> <p>15 non-perineal, there's diaphragm, and there's</p> <p>16 sanitary napkins.</p> <p>17 Q. Well, if you look at</p> <p>18 Penninkilampi under Figure 2 -- on the study</p> <p>19 name. Under Figure 2 it says "any perineal</p> <p>20 talc use."</p> <p>21 Do you see?</p> <p>22 A. I do see that.</p> <p>23 Q. Okay. Do you know what the</p> <p>24 metric was in Gates?</p> <p>25 MS. MILLER: I believe you</p>	<p style="text-align: right;">Page 469</p> <p>1 Q. Right.</p> <p>2 So it's a different metric, is</p> <p>3 it not?</p> <p>4 A. It may or may not be a</p> <p>5 different metric because there is a previous</p> <p>6 publication where the authors felt that this</p> <p>7 was a more reliable measure of exposure of</p> <p>8 ever versus never.</p> <p>9 Q. The point is, Doctor, you were</p> <p>10 critical of Penninkilampi as to why they</p> <p>11 didn't include Gates 2010. And I'm asking</p> <p>12 you: Would that be good reason not to</p> <p>13 include Gates 2010, because it used a</p> <p>14 different metric of exposure?</p> <p>15 MS. MILLER: Objection. Calls</p> <p>16 for speculation.</p> <p>17 THE WITNESS: No, not</p> <p>18 necessarily, because the authors felt</p> <p>19 that this -- that this metric was</p> <p>20 actually a more reliable metric of</p> <p>21 ever versus never.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Okay. In the Gertig study,</p> <p>24 they use ever versus ever talc use.</p> <p>25 MS. MILLER: Objection. You</p>

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<p style="text-align: right;">Page 470</p> <p>1 said ever versus ever.  2 QUESTIONS BY MR. TISI:  3 Q. They used ever use.  4 Gates -- Gertig used ever  5 versus never, correct?  6 A. Gertig? Again, I don't have  7 these memorized, so I'm going to have to look  8 at it to see what we're referring to.  9 Q. But the big question is you  10 don't -- you can't sit here today and tell me  11 why it is that Penninkilampi did not use  12 Gates 2010, can you?  13 It's not in your report, and  14 you can't tell me today?  15 MS. MILLER: Objection. Asked  16 and answered.  17 THE WITNESS: The description  18 of the -- of the pulling of articles  19 for the meta-analysis is described.  20 The replication of that would have to  21 be performed to answer that question.  22 QUESTIONS BY MR. TISI:  23 Q. And you didn't do that, did  24 you?  25 A. For me to -- for me to perform</p>	<p style="text-align: right;">Page 472</p> <p>1 kinds of stuff. You find time for those.  2 My question to you is: Would  3 you find time do this, to submit your point  4 of view to peer review?  5 MS. MILLER: Objection.  6 THE WITNESS: Again, I'm going  7 to have to answer it the same -- the  8 same way, that if an opportunity arose  9 and it seemed like an interesting  10 investigation --  11 QUESTIONS BY MR. TISI:  12 Q. Is it an interesting  13 investigation to you, or is this just  14 something you did for this case?  15 MS. MILLER: Objection.  16 THE WITNESS: This has -- this  17 has been a very interesting exercise  18 in evaluating epidemiology.  19 QUESTIONS BY MR. TISI:  20 Q. And so now having been through  21 the process, do you intend to subject your  22 opinions, particularly the ones where you  23 were very strong in your criticism of those  24 who have published and have put themselves  25 out there, subject your opinions to peer</p>
<p style="text-align: right;">Page 471</p> <p>1 my own meta-analysis by myself would be out  2 of the scope of even performing an analysis  3 per -- a meta-analysis correctly.  4 Q. Doctor --  5 A. I'm going to need a team to do  6 that.  7 Q. Okay. We started our day today  8 talking about publication and, you know,  9 opinions inside and outside litigation and  10 all those questions.  11 Let me ask you this: You spent  12 seven hours with me today. You wrote your  13 report. You've been through this process.  14 Do you intend to publish your  15 views on ovarian cancer and talc?  16 A. I have no idea what I'm going  17 to do in the future. I -- I am a -- I have  18 an active research career in cystic fibrosis  19 and lung transplantation.  20 If the opportunity arose where  21 there was something to publish and seemed  22 interesting, fine, but I can't predict that.  23 Q. Well, you're also pretty busy  24 in litigation. You do four, five cases a  25 year. You do speakers bureaus. You do all</p>	<p style="text-align: right;">Page 473</p> <p>1 review?  2 MR. LOCKE: Objection.  3 THE WITNESS: Well --  4 QUESTIONS BY MR. TISI:  5 Q. Dr. Siemiatycki has put himself  6 out there and submitted himself --  7 MS. MILLER: He started  8 answering the question --  9 QUESTIONS BY MR. TISI:  10 Q. Well, let me ask you this.  11 MS. MILLER: -- and you  12 interrupted him. Can we just end the  13 day with question, answer, question,  14 answer?  15 QUESTIONS BY MR. TISI:  16 Q. Okay. Dr. Siemiatycki  17 published in this, correct?  18 MS. MILLER: Objection.  19 THE WITNESS: I'm going to have  20 to look through what's been published  21 by Dr. Siemiatycki.  22 QUESTIONS BY MR. TISI:  23 Q. Okay. Dr. McTiernan went  24 before Congress and gave her testimony,  25 correct?</p>

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<p style="text-align: right;">Page 474</p> <p>1 MR. LOCKE: Objection.</p> <p>2 THE WITNESS: Again, I told you</p> <p>3 I didn't know about that.</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. Dr. Smith-Bindman said she's</p> <p>6 going to submit her meta-analysis to</p> <p>7 publication.</p> <p>8 Do you remember seeing that?</p> <p>9 A. You'd have to show me where she</p> <p>10 said that.</p> <p>11 Q. Dr. Moorman was a coauthor on</p> <p>12 the Schildkraut study, correct?</p> <p>13 A. I'd have to look back through</p> <p>14 the list of authors to confirm or not</p> <p>15 confirm.</p> <p>16 Q. Some of them wrote Health</p> <p>17 Canada, as counsel pointed out, to express</p> <p>18 their point of views on this in the comment</p> <p>19 period, correct?</p> <p>20 A. I have no idea.</p> <p>21 Q. Do you have any intention, now</p> <p>22 having been through this process, as you sit</p> <p>23 here today, to submit your criticisms and</p> <p>24 your opinions to the criticisms of your</p> <p>25 fellow peers?</p>	<p style="text-align: right;">Page 476</p> <p>1 tell our patients to stop using talcum</p> <p>2 powder, what would you tell them?</p> <p>3 MS. MILLER: Objection.</p> <p>4 THE WITNESS: Again, I -- I'd</p> <p>5 say it depends. If you're talking</p> <p>6 about based on the medical evidence</p> <p>7 out there, there's no evidence to</p> <p>8 suggest that -- and if we're</p> <p>9 specifically talking about risk of</p> <p>10 ovarian cancer --</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Yes.</p> <p>13 A. -- there's no evidence to</p> <p>14 suggest a causal relationship between talcum</p> <p>15 powder and ovarian cancer.</p> <p>16 Q. No evidence whatsoever?</p> <p>17 A. Based on the body of medical</p> <p>18 literature, no, there is not evidence --</p> <p>19 Q. And so you would --</p> <p>20 A. -- but there is a --</p> <p>21 Q. You would tell them --</p> <p>22 MS. MILLER: He's in a middle</p> <p>23 of a sentence.</p> <p>24 THE WITNESS: So what I said is</p> <p>25 it would depend. If we're talking</p>
<p style="text-align: right;">Page 475</p> <p>1 MS. MILLER: Objection.</p> <p>2 THE WITNESS: Submit where?</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. Anywhere. Congress, medical</p> <p>5 meetings, regulatory authorities,</p> <p>6 publications, peer review, your colleagues,</p> <p>7 anywhere.</p> <p>8 MS. MILLER: Objection.</p> <p>9 THE WITNESS: And I'll just</p> <p>10 have to say I have no idea.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Okay.</p> <p>13 A. There's a possibility that</p> <p>14 something may arise in the future and I may</p> <p>15 take up that opportunity. And I don't know</p> <p>16 today.</p> <p>17 Q. Have you gone -- have you gone</p> <p>18 to your oncology department here -- you have</p> <p>19 an oncology department here at -- or a</p> <p>20 gynecology department here at Hopkins?</p> <p>21 A. We do have a --</p> <p>22 Q. Gynecology?</p> <p>23 A. -- a gynecology department.</p> <p>24 Q. Okay. If a gynecology</p> <p>25 department asked you, do you think we should</p>	<p style="text-align: right;">Page 477</p> <p>1 about the medical literature, that</p> <p>2 would be my response, that -- that</p> <p>3 that causal relationship does not</p> <p>4 exist based on the evidence.</p> <p>5 But if a doctor is asking -- if</p> <p>6 a gynecologist is asking me whether or</p> <p>7 not talcum powder should be used for a</p> <p>8 specific patient, it's going to be</p> <p>9 dependent on that specific patient.</p> <p>10 There might be a wound in there.</p> <p>11 There might be some other reason --</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. I'm not asking that.</p> <p>14 A. Well, that's --</p> <p>15 Q. I'm not asking that. I'm</p> <p>16 asking --</p> <p>17 A. But that's what I'm saying.</p> <p>18 You asked me if I would recommend, and so</p> <p>19 I'll telling you that it depends. It</p> <p>20 depends.</p> <p>21 Q. If a gynecologist came to you</p> <p>22 and said, "Doctor, you're an epidemiologist,</p> <p>23 I have women who are asking me whether or not</p> <p>24 I should -- they hear what's on the radio,</p> <p>25 they hear what's on television. They're</p>

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<p>1 aware of a potential link that's been</p> <p>2 discussed out there. Should I tell my women</p> <p>3 to stop or should I tell them to continue</p> <p>4 using it?" what would you tell them?</p> <p>5 Continue using it?</p> <p>6 MS. MILLER: Objection, vague,</p> <p>7 and objection, asked and answered.</p> <p>8 THE WITNESS: So I would ask</p> <p>9 why, and it would be dependent on the</p> <p>10 answer to why.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. If they said because there's a</p> <p>13 concern that they might put myself at</p> <p>14 increased risk of ovarian cancer?</p> <p>15 MS. MILLER: Objection. This</p> <p>16 was asked and answered.</p> <p>17 QUESTIONS BY MR. TISI:</p> <p>18 Q. If they said -- if they said</p> <p>19 that was the reason why, what would you</p> <p>20 answer -- would you respond to them?</p> <p>21 A. I would say, based on the body</p> <p>22 of medical evidence, there is no causal</p> <p>23 association between talcum powder and ovarian</p> <p>24 cancer.</p> <p>25 Q. Okay. So you'd tell them, keep</p>	<p>1 MS. MILLER: Of course.</p> <p>2 MR. TISI: Can you find --</p> <p>3 would you pull them over...</p> <p>4 QUESTIONS BY MS. MILLER:</p> <p>5 Q. We're going to be looking at</p> <p>6 page 11.</p> <p>7 MR. TISI: I'm sorry, he just</p> <p>8 started putting them away.</p> <p>9 MS. MILLER: It's</p> <p>10 understandable. I think everybody</p> <p>11 wants to get home for the weekend.</p> <p>12 QUESTIONS BY MS. MILLER:</p> <p>13 Q. I'm looking at the bottom of</p> <p>14 page -- of page 11 in Exhibit 31.</p> <p>15 Do you recall Exhibit 31 was</p> <p>16 shown to you earlier today?</p> <p>17 A. I do.</p> <p>18 Q. And this is a document from the</p> <p>19 National Cancer Institute; is that correct?</p> <p>20 A. That's what it appears to be.</p> <p>21 Q. The title is "Ovarian,</p> <p>22 Fallopian Tube and Primary Peritoneal Cancer</p> <p>23 Prevention," correct?</p> <p>24 A. Correct.</p> <p>25 Q. There's a section on page 11</p>
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<p>1 dusting?</p> <p>2 MS. MILLER: Objection.</p> <p>3 THE WITNESS: I didn't say</p> <p>4 that. I said based on the body of</p> <p>5 medical evidence, there is no</p> <p>6 association, causal association,</p> <p>7 between talcum powder and ovarian</p> <p>8 cancer.</p> <p>9 There may be other reasons that</p> <p>10 that gynecologist would or would not</p> <p>11 recommend using talcum powder.</p> <p>12 MR. TISI: Doctor, I appreciate</p> <p>13 your time today. I have no further</p> <p>14 questions.</p> <p>15 Anything else? Do you have any</p> <p>16 questions?</p> <p>17 MS. MILLER: We're discussing</p> <p>18 it. I just have two questions.</p> <p>19 CROSS-EXAMINATION</p> <p>20 QUESTIONS BY MS. MILLER:</p> <p>21 Q. Can you go back to Exhibit 31?</p> <p>22 A. 31.</p> <p>23 Q. Okay. Can you turn to --</p> <p>24 MR. TISI: Can you wait until I</p> <p>25 get my copy, Counsel?</p>	<p>1 titled "Perineal Talc Exposure."</p> <p>2 Do you see that?</p> <p>3 MR. TISI: It's on page 11? I</p> <p>4 don't see it on page 11.</p> <p>5 MS. MILLER: Page 11 of 17.</p> <p>6 QUESTIONS BY MS. MILLER:</p> <p>7 Q. Do you see that section?</p> <p>8 MR. TISI: No, I don't,</p> <p>9 actually. Can you show me?</p> <p>10 THE WITNESS: I do.</p> <p>11 MR. TISI: I see oophorectomy</p> <p>12 on page 11.</p> <p>13 MS. MILLER: You've got --</p> <p>14 you've got a different version than</p> <p>15 the one you used as an exhibit. It's</p> <p>16 on page 11 of the one you used as an</p> <p>17 exhibit.</p> <p>18 MR. TISI: Okay. I'll have to</p> <p>19 argue this when we're done.</p> <p>20 QUESTIONS BY MS. MILLER:</p> <p>21 Q. Did counsel direct you to this</p> <p>22 section of the exhibit when he was</p> <p>23 questioning you about it?</p> <p>24 MR. TISI: Objection to form.</p> <p>25 THE WITNESS: Not that I</p>

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<p>1 recall.</p> <p>2 QUESTIONS BY MS. MILLER:</p> <p>3 Q. Did you see this section when</p> <p>4 you were asked questions about this document?</p> <p>5 MR. TISI: Objection to form.</p> <p>6 THE WITNESS: Not that I</p> <p>7 recall.</p> <p>8 QUESTIONS BY MS. MILLER:</p> <p>9 Q. Can you read the first sentence</p> <p>10 under Perineal Talc Exposure?</p> <p>11 A. Sure.</p> <p>12 "The weight of evidence does</p> <p>13 not support an association between perineal</p> <p>14 talc exposure and an increased risk of</p> <p>15 ovarian cancer."</p> <p>16 Q. Can you read the second</p> <p>17 sentence?</p> <p>18 A. "Results from case control and</p> <p>19 cohort studies are inconsistent."</p> <p>20 MS. MILLER: I have no further</p> <p>21 questions at this time.</p> <p>22 MR. TISI: May have it, please?</p> <p>23 MS. MILLER: Well, don't take</p> <p>24 his because --</p> <p>25 MR. TISI: Well, okay, can I</p>	<p>1 exposure it has footnotes 43, 44, 45 and 46.</p> <p>2 Do you see that?</p> <p>3 A. Okay.</p> <p>4 Q. Do you see that?</p> <p>5 A. Yeah, I see 42 through 45, yes.</p> <p>6 Q. And if you go to the back of</p> <p>7 the thing where they -- the back of this --</p> <p>8 they only looked at four studies.</p> <p>9 Do you see that?</p> <p>10 A. What are you referring to?</p> <p>11 Q. Well, the footnotes, they look</p> <p>12 at 43, 44, 45 and 46. They have four</p> <p>13 references: Huncharek, Terry, Gertig and</p> <p>14 Houghton.</p> <p>15 One is the Huncharek study</p> <p>16 which in your footnote in your report you</p> <p>17 indicated you agree that there are mistakes</p> <p>18 in those, right?</p> <p>19 MS. MILLER: Objection.</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. You looked at the report of</p> <p>22 April Zambelli-Weiner, correct?</p> <p>23 A. I did look at that, yes.</p> <p>24 Q. Okay. And you agree that there</p> <p>25 were mistakes in that?</p>
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<p>1 have -- may I have yours then?</p> <p>2 MS. MILLER: Well, mine is</p> <p>3 marked.</p> <p>4 MR. TISI: Okay. Well, I --</p> <p>5 MS. MILLER: You don't have it?</p> <p>6 MR. TISI: I don't. I have the</p> <p>7 different copy.</p> <p>8 MS. MILLER: If you give it to</p> <p>9 me, I'll show you what page it is.</p> <p>10 REDIRECT EXAMINATION</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. All right. So, Doctor, first</p> <p>13 of all, you testified earlier you don't even</p> <p>14 know who these authors are who did this,</p> <p>15 correct?</p> <p>16 MR. LOCKE: Objection.</p> <p>17 QUESTIONS BY MR. TISI:</p> <p>18 Q. Earlier?</p> <p>19 MS. MILLER: Objection.</p> <p>20 THE WITNESS: It looks like</p> <p>21 this is from the National Cancer</p> <p>22 Institute, but I don't know who put</p> <p>23 this all together.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. So now in the perineal talc</p>	<p>1 MS. MILLER: Objection.</p> <p>2 THE WITNESS: The numbers may</p> <p>3 have been off, but the general gist of</p> <p>4 the trend was still the same, meaning</p> <p>5 the numbers didn't affect statistical</p> <p>6 significance, as I recall.</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. And this is not -- this</p> <p>9 study -- studies four -- it has four</p> <p>10 references. You have some 30 --</p> <p>11 MS. MILLER: We're out of time.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. You have some 30 references.</p> <p>14 Are you going to tell me that</p> <p>15 they did a full causation analysis that you</p> <p>16 did?</p> <p>17 MS. MILLER: Objection. And</p> <p>18 we're out of time.</p> <p>19 MR. TISI: You're not going to</p> <p>20 let him answer that question?</p> <p>21 MS. SHARKO: He can answer that</p> <p>22 one question.</p> <p>23 MR. TISI: Thank you.</p> <p>24 THE WITNESS: I don't know what</p> <p>25 they did here.</p>

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<p style="text-align: right;">Page 486</p> <p>1 MR. TISI: Thank you very much. 2 I appreciate it. 3 VIDEOGRAPHER: Okay. That's 4 it. 5 MS. MILLER: Thank you. 6 VIDEOGRAPHER: The time is 7 6:01 p.m., April 18, 2019. Going off 8 the record, completing the videotaped 9 deposition. 10 (Deposition concluded at 6:01 p.m.) 11 ----- 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 488</p> <p>1 INSTRUCTIONS TO WITNESS 2 3 Please read your deposition over 4 carefully and make any necessary corrections. 5 You should state the reason in the 6 appropriate space on the errata sheet for any 7 corrections that are made. 8 After doing so, please sign the 9 errata sheet and date it. You are signing 10 same subject to the changes you have noted on 11 the errata sheet, which will be attached to 12 your deposition. 13 It is imperative that you return 14 the original errata sheet to the deposing 15 attorney within thirty (30) days of receipt 16 of the deposition transcript by you. If you 17 fail to do so, the deposition transcript may 18 be deemed to be accurate and may be used in 19 court. 20 21 22 23 24 25</p>
<p style="text-align: right;">Page 487</p> <p>1 CERTIFICATE 2 3 I, CARRIE A. CAMPBELL, Registered 4 Diplomate Reporter, Certified Realtime 5 Reporter and Certified Shorthand Reporter, do 6 hereby certify that prior to the commencement 7 of the examination, Christian Merlo, MD, MPH 8 was duly sworn by me to testify to the truth, 9 the whole truth and nothing but the truth. 10 I DO FURTHER CERTIFY that the 11 foregoing is a verbatim transcript of the 12 testimony as taken stenographically by and 13 before me at the time, place and on the date 14 hereinbefore set forth, to the best of my 15 ability. 16 17 I DO FURTHER CERTIFY that I am 18 neither a relative nor employee nor attorney 19 nor counsel of any of the parties to this 20 action, and that I am neither a relative nor 21 employee of such attorney or counsel, and 22 that I am not financially interested in the 23 action. 24 25 CARRIE A. CAMPBELL, NCRA Registered Diplomate Reporter Certified Realtime Reporter Notary Public Dated: April 19, 2019</p>	<p style="text-align: right;">Page 489</p> <p>1 ACKNOWLEDGMENT OF DEPONENT 2 3 4 I, _____, do 5 hereby certify that I have read the foregoing 6 pages and that the same is a correct 7 transcription of the answers given by me to 8 the questions therein propounded, except for 9 the corrections or changes in form or 10 substance, if any, noted in the attached 11 Errata Sheet. 12 13 14 15 Christian Merlo, M.D., MPH      DATE 16 17 Subscribed and sworn to before me this 18 _____ day of _____, 20 _____. 19 My commission expires: _____ 20 21 Notary Public 22 23 24 25</p>

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Page 490		
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2	ERRATA	
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4	PAGE	LINE CHANGE/REASON
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2	LAWYER'S NOTES	
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